Schedule 10 – List of Names/Officials Named in Report

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Name	Title	Company/Year
Allen, Shari	Regulatory Affairs Manager	BPV 2004
	Director RA/CA	BPV 2005-2006
Baird, Brett	Senior Product Manager Marketing Manager	BPV 2007 BPV 2008-2011
Balutowski, Genevieve	RA Associate	BPV 2003-2004
	RA Specialist	BPV 2005
	Senior RA Specialist	BPV 2006-2007
	Regulatory Affairs Associate Project Manager	
Barry, Brian	Vice President, Regulatory/Clinical Affairs & Quality Assurance	Bard Access Systems 1994-1997
	Vice President, Corporate Regulatory Affairs	C.R. Bard 1997-2000
	Vice President of regulatory Affairs and Clinical Affairs	C.R. Bard 2003-2007
Beasley, Jim	President	BPV 2007-2008
	President & Group Vice President	BPV 2009-2011
Benware, Charlie	Engineer	BPV 2003 - 2005
Boyle, Kevin	Vice President R & D	BPV 2013-2015
Cano, David	Vice President Human Resources	BPV 2014-2015
Carr, Rob	Program Director	BPV 2005, 2008-2009
	Director, Technology Acquisition & Integration	BPV 2006-2007
	Director R&D Biopsy	BPV 2010-2012
	Senior Director R&D Biopsy & Imaging	BPV 2013-2014
	Vice President International	BPV 2015
Chanduskzko, Andrzej	Senior Engineer, R&D Staff Engineer	BPV 2004-2008
	Staff Engineer	BPV 2009-2014
	Principal Engineer	BPV 2015
Conrad, Garth	Vice President Quality Assurance	C.R. Bard Corp. 2015
Coval-Goldsmith, Sherrie	Vice President of Regulatory Affairs	BPV 1999 - 2000
DeCant, Len	Vice President Research & Development	BPV 2004-2006
DeFord, John	Vice President of Science and Technology	C.R. Bard 2004-2007
DeJohn, Joe	Vice President Sales	BPV 2003-2006
	Vice President Domestic Sales	BPV 2005-2006

Name	Title	Company/Year
	Western Regional Manager, Interventional	BPV 2004
DeLeon, Robert	Western Regional Manager	BPV 2006-2007
Doherty, Brian	Director Domestic Sales	BPV 2008-2009
	Vice President Domestic Sales	BPV 20010-2011
	Vice President Sales & Marketing	BPV 2012
Edwards, Mary	Vice President RA/CA	C.R. Bard 2003-2005
Fitzpatrick, Ed	Engineering/Business Development Leader	C.R. Bard 1986- Present
Fuller, Kay	Senior Regulatory Specialist	BPV 1999-2004
Ganser, Christopher D.	Vice President, Regulatory/Science	C.R. Bard 2005-2006
	Vice President Quality, Environmental Services & Safety	C.R. Bard 2007-2010
Glass, Holly	Vice President Government & Public Relations	C.R. Bard 2002-2009
Graves, Micky	Senior Engineer	BPV 2005
	Staff Engineer	BPV 2006-2008
	District Sales Manager	
Greer, Jason	Delta Plains District Manager	BPV 2005-2007
	Controller Finance	BPV 2012
Hammond, Kimberly	Vice President & Controller Finance	BPV 2012-2015
Hudnall, Janet	Sr. Marketing Manager	C.R. Bard 2006-2008
	Marketing Manager	C.R. Bard 2004-2006
	Sr. Product Manager	C.R. Bard 2002- 2004
	Product Manager	C.R. Bard 2001 -2002
	Project Engineer	C.R. Bard 1998- 2001
Hudson, Brian	Quality Engineer Endovascular	BPV 2003-2007
	Senior Risk Manager	BPV 2008-2011
	Associate Director Quality Assurance	BPV 2012
Hutchison, Karen	Senior Regulatory Specialist	BPV 2005-2006
Jones, Kellee	Executive Administrative Assistant	BPV 2004
Kondrosky, John	Vice President & General Manager Biopsy	BPV 2010-2011
Krueger, Bill	Vice President & Controller Finance	BPV 2004-2011
Lapid, Inbal	Engineer I	BPV 2006

Name	Title	Company/Year
Lemaster, Jeff	Vice President Marketing	BPV 2014-2015
Little, Bill	Vice President Global Marketing	BPV 2008-2011
McDermott, John	President	BPV 2003 -2006
Modra, Chad	Director Quality Assurance	C.R. Bard Corp. 2011
	Vice President Quality Assurance	C.R. Bard Corp. 2012-2014
Mukherjee, Avijit	Program Manager	BPV 2004-2005
O'Brien, Paddy	Director Sales Biopsy	BPV 2012
	Vice President Sales	BPV 2013, 2015
Raji-Kubba, Abithal	Vice President Research & Development	BPV 2007-2010
	Vice President Lutonix Technology Center	BPV 2011-2012
Randall, Scott	Program Manager	2009-2011
	Associate R&D Director	2012-2014
	Director R&D	2015
Rausch, David	National Sales Training Manager	BPV 2003
	National Sales Training Manager	BPV 2003
Rickenbaugh, Carl	Director Business Development	BPV 2007-2012
	Vice President Business Development	BPV 2012-2015
Ring, Tim	CEO	
Salzmann, Dennis	Regulatory Affairs	BPV 2005-2009
Schultz, Gin	Vice President Quality Assurance	C.R. Bard Corp. 2005-2010
Shifrin, Kevin	Vice President Global Marketing	BPV 2004-2007
Simpson, Charles	Program Director, Interventional	BPV 2004-2007
Spicer, Jeff	Managing Director Angiomed GmbH & Company	BPV 2008-2015
Sullivan, Jack	South Regional Manager Central Regional Manager Western Regional Manager	BPV 2005 BPV 2006-2009 BPV 2010-2011
Terlizzi, Mike	Vice President Sales & Marketing Bard Biopsy Systems	BPV 2005-2009
Tessmer, Alex	Research & Development Engineer (Project Engineer II)	BPV 2003-2004
Uelmen, Doug	Vice President Quality Assurance	BPV 2003-2005
Van Vleet, John	Vice President RA/CA	C.R. Bard Corp. 2007-2015

Name	Title	Company/Year
Vierling, Carol	Director, Regulatory Affairs	BPV 1994-2002
Walaska, Mark	Vice President Manufacturing	BPV 2004-2008
	Staff Vice President Manufacturing	C.R. Bard Corp. 2009-2015
Walcott, Cindi	Senior Manager Clinical Assurance	BPV 2008-2011
Warren, Mike	Vice President Human Resources	BPV 2005-2012
Weiland, John	COO	BPV
Williamson, Steve	President	BPV 2012-2015
Wong, Natalie	Senior Quality Engineer, New Product Development	BPV 2004-2007
	Quality Engineering Manager	BPV 2008-2011

Schedule 11 – Deposition Citations

Schedule 11 – Deposition Citations

Paragraph	Deponent	Deposition Date	Page:Line
68	Donna B. Tillman	6/12/2014	101:20-23; 116:1-3; and 120:6-7
70	Gin Schultz	1/30/2014	81:18-82:24
Footnote 15	Murray Asch, M.D.	5/2/2016	109:23-111:8
113	Robert Carr	12/19/2014	240:6-17
114	Robert Carr	12/19/2014	241:12-242:6
Footnote 37	Andrzej Chanduszko	10/10/2013	242-243
156	Gin Schultz	10/10/2013	166:22-167:20
Footnote 41	Chad Modra	3/28/2013	181:1-19
176	John Lehmann, M.D., M.P.H.	4/2/2013	282:16-283:2
Footnote 56	Andrzej Chanduszko	10/10/2013	227:7-25
Footnote 57	David W. Feigal, Jr., M.D.	9/1/2016	65:14-21
Footnote 57	David W. Feigal, Jr., M.D.	9/1/2016	71:18-23
Footnote 57	David W. Feigal, Jr., M.D.	9/1/2016	72:4-23
Footnote 57	David W. Feigal, Jr., M.D.	9/1/2016	73:12-74:7
546	Clement J. Grassi	7/30/2014	124:21-125:18
Footnote 88	Murray Asch, M.D.	1/5/2011	67:7-20

Deposition of Donna B. Tillman, 6/12/2014, Kessler Report Paragraph 68

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Q. Okay. Is it the manufacturer's post-market role to ensure that any 510(k) cleared device it sells remains safe and effective, adequately labeled, and adequately manufactured and monitored throughout the entire length of its intended use?
MR. ROGERS: Object to form.
A. So the manufacturer is responsible for ensuring that the device continues to be safe and effective and that they meets FDA's quality system requirements throughout the life of the device.
Q. Don't start changing my questions,

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ma'am, or I'm going to start changing your answers, and that wouldn't be fair to either one of us.
So my question is, is it the manufacturer's post-market role to ensure that any 510(k) cleared device it sells remains safe and effective, adequately labeled, and adequately manufactured and monitored throughout the entire length of its intended use?
MR. ROGERS: Object to the form.
Q. Yes or no?
A. I don't know what you mean by adequately labeled and monitored. So that's – I guess I'm going to have to answer the question no, then.

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Q. Would you agree that the Recovery filter that we're talking about in this case, and in the 510(k) submission to actually be better than the Simon Nitinol filter's predicate device but it could not be worse and/or introduce new safety issues for patients that had not been addressed by the manufacturer or were seen with the Simon Nitinol filter?
MR. ROGERS: Object to the form.
A. I don't agree with the statement – question as stated. The device – the Recovery filter needs to be substantially equivalent to the predicate device. That doesn't mean it needs to be the same in all respects.
Q. Okay. Well, I didn't ask you that, ma'am. I was specific about my question.
My question is, the Recovery filter could actually be better than the Simon Nitinol filter but it could not be worse; true?
A. It has to be substantially equivalent.
Q. Okay. But it could be better from a safety and effectiveness standpoint but it could not be worse; is that a true statement?

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A. Assessed overall, the safety and effectiveness of the device could not be worse than the predicate device.

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answer that question.
(Record read.)
A. I believe I answered that question where I said I've certainly seen information that demonstrates that the Recovery filter is going to have different performance when compared to the Simon Nitinol filter.
Q. Okay. Let me ask you specifically, where in any of the material you've reviewed that was submitted as part of the 510(k) requirement where Bard specifically stated that our Recovery filter may not be as safe and

effective as our Simon Nitinol filter?
MR. ROGERS: Object to the form.
A. That information was not provided in the 510(k), and I don't believe that's what I said.
Q. Okay. But that's what I'm asking?
A. Yeah. So I don't believe that there's any information in the 510(k) that suggests that the Recovery filter is not as safe and effective as the SNF filter.
Q. Okay. But you've actually see documents where whoever was involved in this

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510(k) process at FDA, where FDA stated that the Recovery filter is required to be as safe and as effective as the Simon Nitinol filter; true?
A. As I think we already – yes. That in order to demonstrate substantial equivalence, the Recovery filter needs to be as safe and effective as the predicate device.
Q. Okay. And, again, there's nothing that you've seen where Bard has even implied that our Simon Nitinol filter in the real world, once we start selling it, is not expected to be as safe and as effective as our Simon Nitinol filter in any respect; true?
MR. ROGERS: Object to the form.
A. True, I've not seen any situations where Bard says that their device is not as safe and effective as the SNF filter, I agree with that.
Q. Have you seen anything in the 510(k) application where Bard makes any kind of statement or representation that raises different questions of safety and effectiveness in comparing its Recovery to the Simon Nitinol filter?

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A. No.
Q. Ma'am, would you agree that in order for it to be a legally – a legal and appropriate predicate device, it must be a device that has not been removed from the market or determined to be misbranded or adulterated?
A. When you say "it," you just mean in general, a device cannot be a predicate if it has been removed from the market or has been misbranded or adulterated, is that the question?
Q. Yes.
A. So the second part of that question is true. The question about why it had been removed from the market would have an impact on that. If a company simply decided to stop selling a device, it can still be a predicate.

Deposition of Gin Schultz, 1/30/2014, Kessler Report Paragraph 70

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Q. Okay. And then there – was it the Recovery filter, which had been modified to make it retrievable, correct?
A. The RNF filter was part of – it was a purchased product, and it wasn't built off the platform of the Simon Nitinol. It looks different than the Simon Nitinol, the SNF filter. It was purchased from NMT, and I don't remember what that – it's something technologies. And I can't remember.
Q. You say it wasn't built off the platform of the SNF?
A. Yeah, so they didn't take the SNF filter and say, "Let's modify these features on it. And we're going – and from that, we're going to – we're going to come from the RNF filter."

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Q. What –
A. It was different materials. It looks different. The Simon Nitinol has, like, little loops in the inside cage. The RNF had what they call arms and legs. There was no loops in it. So they had the arms that were hanging down, and the legs were longer. It was taller, slimmer. It looked different.
Q. Okay. Other than looks, are you basing that statement off of anything else?
MR. NORTH: Objection to the form.
MR. BRENES: Hold on. Let me finish, Richard.
BY MR. BRENES:
Q. Did you review materials that told you it was not a line extension of the SNF?
A. I did not review materials, but I know that the RNF was a purchased technology and the Simon Nitinol was a technology that Bard had preexisting.

Deposition of Murray Asch, M.D., 5/2/2016, Kessler Report Footnote 15

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14 Q. Are you aware of any documents that
15 actually describe what Bard's responsibility is, what
16 NMT's responsibility is with respect to the Recovery
17 filter or for that matter the Simon Nitinol filter?
18 A. No. I had no information as to the
19 relationship with Bard, NMT and the filters.
20 Q. But was it your understanding
21 throughout, even from the beginning until you completed
22 this study that – well, actually let me rephrase that.
23 At least in the first year or two of the
24 study, it was your understanding that this was a joint

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1 venture between NMT and Bard, correct?
2 MR. NORTH: Obtain to the form.
3 THE DEPONENT: Yes, that was my
4 impression.
5 BY MR. LOPEZ:
6 Q. In fact, who paid you for your –
7 the time and expenses on this study?
8 A. It was Bard Canada that paid me.
9 Q. Okay. And did they pay you by the
10 hour?
11 A. Yes.
12 Q. And they paid you for the time that
13 you spent relating to this pilot study?
14 A. Yes.
15 Q. So if you – I'm sorry?
16 A. Yeah. So in terms of submitting
17 various forms, following up patients, keeping
18 documents, communicating and providing information.
19 Q. If you had meetings with them,
20 you'd bill for that time?
21 A. Yes.
22 Q. If you had to travel, would they
23 cover your expenses as well as your time?
24 A. Yes, they did.

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1 Q. And even if you had group meetings,
2 team meetings with respect to the pilot study, anything
3 like that, anything that had anything to do with this
4 study, you would be able to bill for your time?
5 MR. NORTH: Objection to the form.
6 BY MR. LOPEZ:
7 Q. Right?
8 A. That's correct.
9 Q. Just like you are billing for your
10 time for this deposition?
11 A. That's correct.
12 Q. Before your last deposition, I
13 believe it was in 2011, did you meet with any
14 representatives from Bard, meaning their lawyers?
15 A. I believe there was a telephone
16 conversation prior to the last deposition.
17 Q. Okay. And the – did they, prior
18 to this deposition, at any time, ask to meet with you
19 to discuss your testimony today?
20 A. No. No one from Bard contacted me
21 prior to today's deposition.
22 Q. Had they done so, would you have
23 agreed to meet with them?
24 A. I would have been pleased to meet

Page 112

1 with them.
2 Q. And would you have told them the
3 same things that you told us when we met with you?
4 A. Absolutely.
5 Q. And would you have told them the
6 same things that you've testified to here today, had
7 they asked you the same questions?
8 MR. NORTH: Objection. Leading.
9 THE DEPONENT: Yes, I would.

Deposition of Robert Carr, 12/19/2014, Kessler Report Paragraph 113 and 114

Page 239

7 MR. BRENES: I'm going to hand you what we'll
8 mark as Exhibit number 14.
9 (Whereupon, Exhibit 14 was marked for
10 identification.)
11 (Reporter's Note: The final Exhibit 14 as marked by the
12 reporter at the deposition does not contain the first
13 document mentioned below, Bates numbers starting with
14 BPV-17-01-00031162, as it was later modified herein.)
15 BY MR. BRENES:
16 Q For the record, it is two separate documents,
17 I'm combined them in one exhibit. The first one starts
18 with BPV-17-01-00031162, and it is a three-page
19 document. The second one starts at BPV-17-01-00031151,
20 and ends at Bates number 160.
21 Mr. Carr, do you recognize these documents?
22 A Yes.
23 Q Okay. What are they?
24 A They're animal study notes.

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1 Q And did you review these in order to prepare
2 for today's deposition?
3 A Yes.
4 Q Okay, and –
5 A I don't think I see the one... Oh, okay.

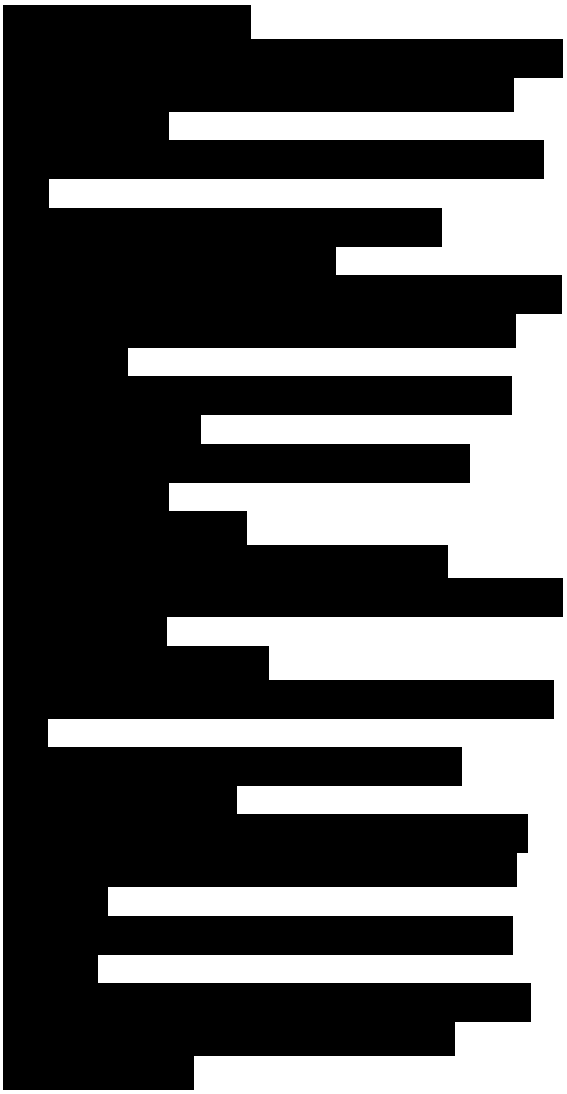
[redacted]

[redacted]

Page 241

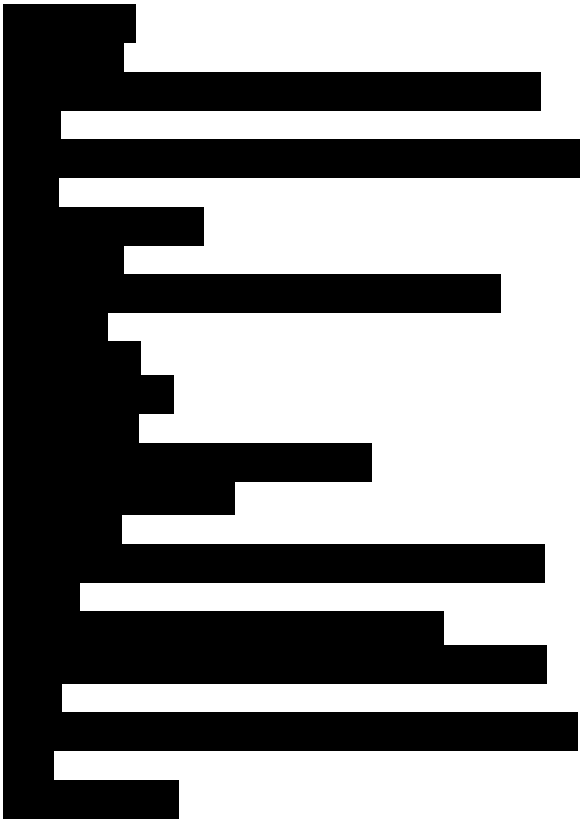
[redacted]

Page 242



24 Q Okay. I'm talking about what was told to the

Page 243



Deposition of Andrzej Chanduszko, 10/10/2013, Kessler Report Footnote 37

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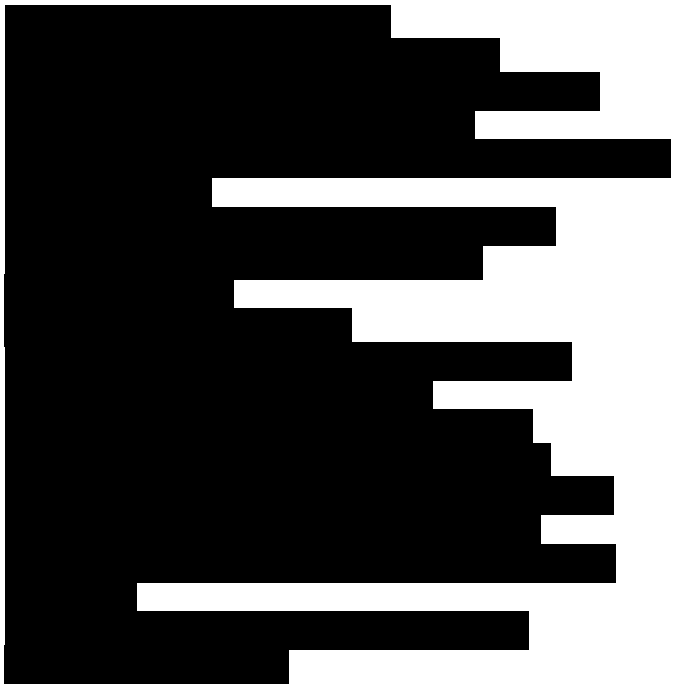

Deposition of Chad Modra, 3/28/2013, Kessler Report Footnote 41

Page 180

20 Q. Turn to the fourth page, Bates range
21 ending 2826, the same document, please.
22 The very bottom row, the date is
23 4/14/2004.
24 A. Okay. Yes.

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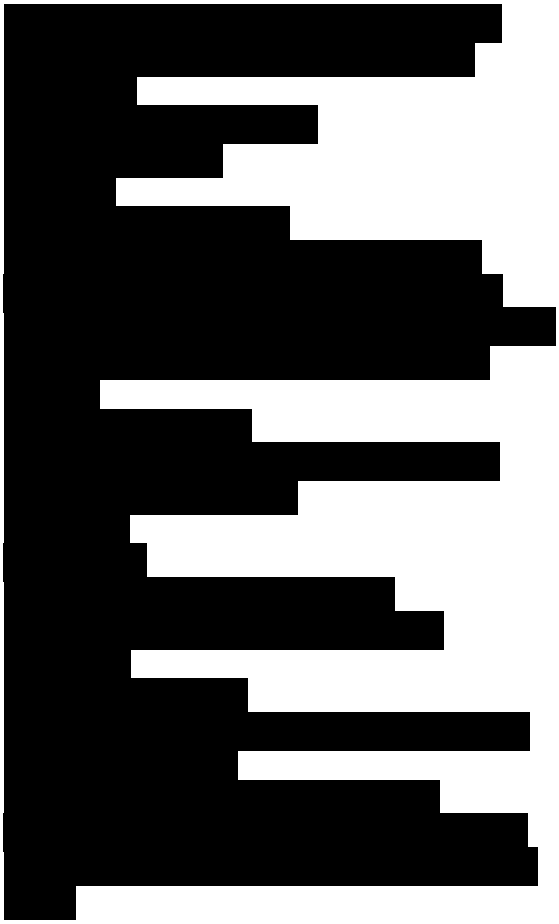

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1 MR. NORTH: Objection to the form.
2 Outside the scope.
3 THE WITNESS: I don't know.

Deposition of Gin Schultz, 10/10/2013, Kessler Report Paragraph 156

Page 166

22 Q. Do you know what an
23 adulterated product is?
24 A. It's product that doesn't

Page 167

[redacted]

Page 168

[redacted]

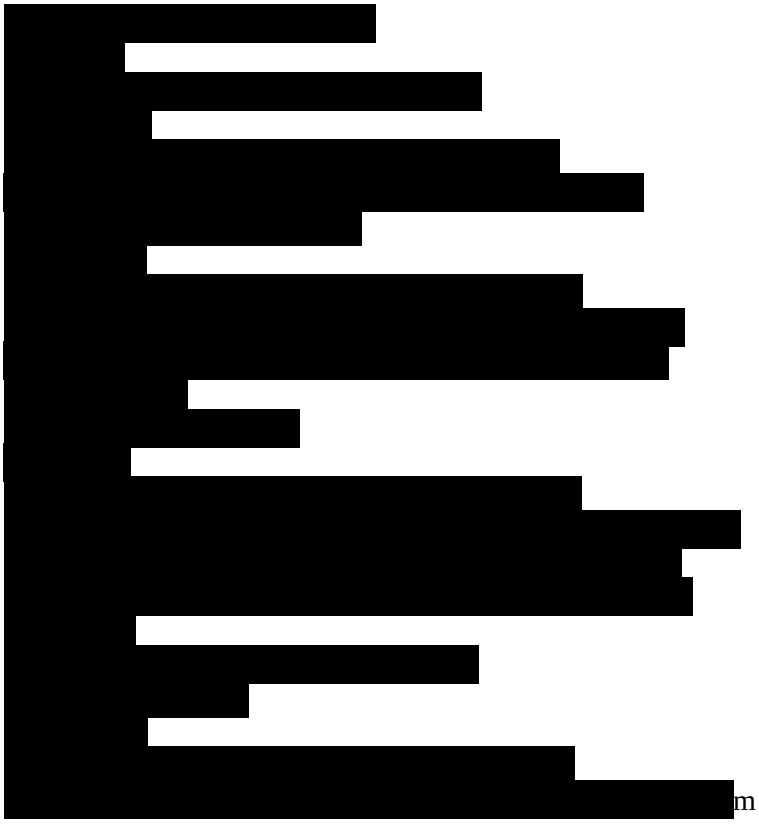
[redacted]

Page 169

[redacted]

Deposition of John Lehmann, M.D., M.P.H., 4/2/2013, Kessler Report Paragraph 176

Page 282



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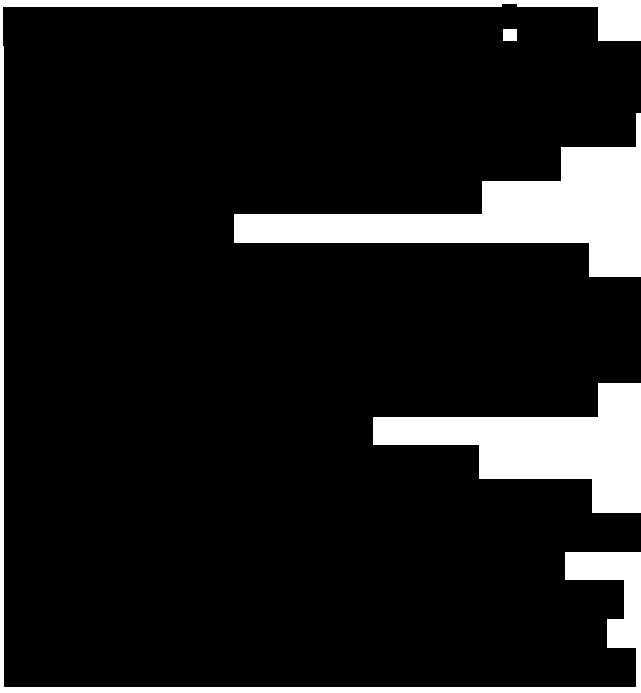

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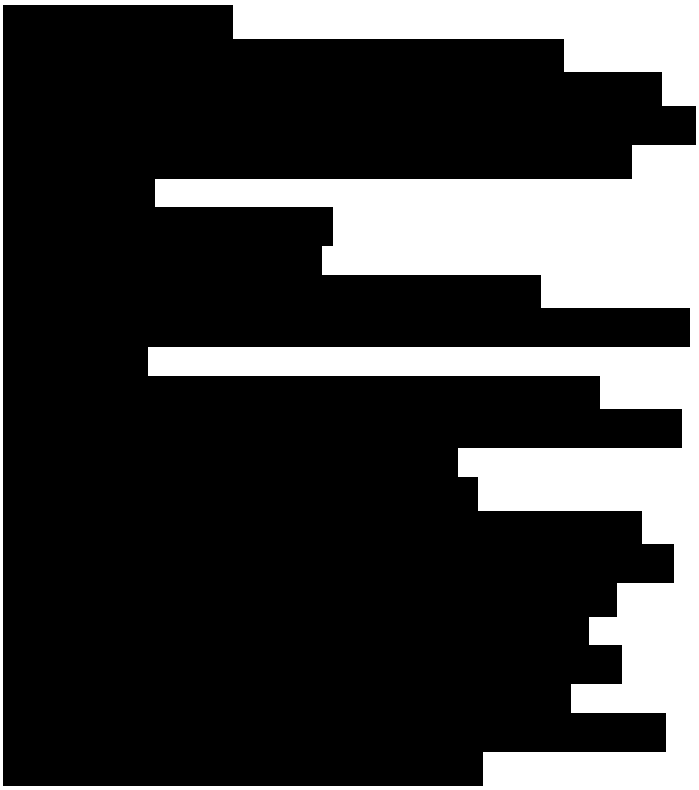

Deposition of Andrzej Chanduszko, 10/10/2013, Kessler Report Footnote 56

Page 227

7 MR. BRENES: I'm going to hand you what
8 will be marked as Exhibit Number 9.
9 (Marked for identification Exhibit 9.)
10 MS. DALY: Thanks.
11 THE WITNESS: Thank you.
12 BY MR. BRENES:
13 Q. Have you seen this document before?
14 A. Yes, I have.
15 Q. Okay. And is it the test report regarding
16 the comparative migration resistance between the
17 Recovery Filter and the other available inferior vena
18 cava devices?
19 A. That's correct.
20 Q. And it was done in early 2004, right?
21 A. I think it was March, is I believe, 2004, is
22 the month when they – when the report was written.
23 Q. In March 2004?
24 A. That would be my best guess, just looking
25 at the dates here.

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Deposition of David W. Feigal, Jr., M.D., 9/1/2016, Kessler Report Footnote 57

Page 64

16 Q. Typically, drug and device manufacturers do
17 investigate those signals; right? I've seen that with
18 Bard to some degree. They're looking into whatever
19 happened with those death cases we talked about earlier;
20 right?
21 A. Yes.
22 Q. One thing they can do is investigate by
23 conducting more formal epidemiology studies such as
24 those you described earlier and you've at times
25 recommended for your clients?

Page 65

1 A. That's right. Or they can see if those such
2 studies exist in the medical literature.
3 Q. They could use healthcare databases?
4 A. They can. It's much more difficult with
5 medical devices than drugs because the insurance
6 companies track pharmacy records much better than they
7 track medical devices.
8 Q. But if there are two products for which they
9 have the records of the sales and where they go, that
10 takes away a little of that tracking difficulty;
right?
11 A. For a given company, they do – they do
12 generally know their sales, yes, for their products but
13 not for anybody else's.
14 Q. And while we're on that subject, I know you've
15 had some criticism in the past of some of the
16 uncertainties related to how the IMS data is produced
17 and whether their samples are generally applicable
18 across the board. But IMS wouldn't be a factor when a
19 company is looking at its own sales of its own products;
20 right?
21 A. That's correct.

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6 Q. As far as you know, Dr. Dal Pan has an
7 excellent reputation?
8 A. Yes. As I recall, he's written a chapter in
9 Dr. Strom's textbook.
10 Q. Have you read that chapter?
11 A. Yes.
12 MR. ARBITBLIT: Mark that.
13 MR. LOPEZ: That's 6.
14 (Plaintiff's Exhibit No. 6 was marked for
15 identification.)
16 THE WITNESS: Well, ask and you shall receive.
17 MR. ARBITBLIT: Not always.
18 Q. So if you look at – so No. 6 is a chapter from
19 Strom's Fifth Edition of "Pharmacoepidemiology,"
20 Chapter 10, "Postmarketing Spontaneous Pharmacovigilance
21 Reporting Systems," lead author Gerald Dal Pan,
22 coauthors Marie Lindquist and Kate Gelperin; correct?
23 A. Yes.
24 Q. You've read this chapter before?
25 A. Yes.

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1 Q. When did you first read it?
2 A. I don't recall. But probably shortly after the
3 textbook came out.
4 Q. And if you turn to page 139, on the right-hand
5 column, at the bottom, the paragraph starting with
6 "Responsibility," could you read that into the record?
7 A. "Spontaneous adverse events, adverse drug
8 reaction reports, have at times served as necessary and

sufficient basis for regulatory actions including
product withdrawals."
Q. And you've read that statement before?
A. Yes.
Q. And you agree with it?
A. Yes, that's true.
Q. And then could you read the next sentence?
A. "In August 2001, the manufacturer of cerivastatin withdrew the drug for marketing based on a markedly increased reporting rate of fatal rhabdomyolysis compared to other drugs in the statin class."
Q. Do you recall that episode taking place while you were at the FDA in 2001?
A. I do.
Q. Rhabdomyolysis that's mentioned there is a muscle disease that cause the contents of muscle cells

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to overload the kidneys resulting in kidney failure and death in some circumstances; is that right?
A. Yes, that's right.
Q. That condition was sufficiently uncommon that it had not been identified as an adverse event associated with the drug in premarket clinical trials; correct?
A. I think that's correct. I don't recall exactly. I mean, all of the statins can produce muscle damage, but not to the severity and extent that it did in the case of this drug.
Q. So do you recall having any opposition to the decision to withdraw Baycol based on reporting rate analysis?
A. No, I didn't disagree with that.
Q. You were aware that the manufacturer Bayer publicly described the withdrawal of Baycol as voluntary?
A. Yes.
Q. So there's no doubt, is there, that the manufacturer in response to a signal and reporting rate analysis has the authority to withdraw its product from the market based on spontaneous event reporting without waiting for the reports of epidemiologic studies?
A. Yes, that's correct. A company can withdraw

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its product for any reason at any time.
Q. Even though the data from the spontaneous event reporting system constituted reporting rates rather than actual adverse event rates with complete numerators and denominators, you did not disagree with the decision to withdraw that product from the market; is that correct?
A. That's correct.
Q. In the 15 years since then, you've never expressed in any public forum some disagreement with the decision to withdraw Baycol from the market in 2010; is that right?
A. No, I have not. I actually do comment on it. I don't remember if it's in this report, but part of what was the case with this was that the reporting rate was known. And the reporting rate, as I recall, was approximately 35, 38 percent, of all cases. So with that respect, the data was much more reflective of what was – what the actual risk was because they had such a high proportion of the patients reported.

Deposition of Clement J. Grassi, 7/30/2014, Kessler Report Paragraph 546

Page 123

Q. How about Dr. Ashe, have you ever spoken to Dr. Ashe?
A. No, I haven't.
Q. And you've read declarations and depositions of Dr. Ashe?
A. Yes, I'm aware of a deposition of his.
Q. Aren't you aware of a declaration of his as well where he was advocating that there should be widespread medical monitoring of the Recovery and G2 devices?
A. Yes, I've heard that referenced.
Q. Well, I mean, you provided a counter-declaration to that, didn't you?
A. You have to let me think about that. To which – just refresh my memory, if you would. To which declaration are you referring to?
Q. Well, there was a – in litigation last year in California where it was being proposed that there should be patient-wide monitoring of people with Recovery and G2 filters

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to determine their current status and determine whether or not there were any fractures or any potential evidence that there – that might be causing problems now or in the future. Do you remember that now?
A. Yes. I did provide a declaration for the group in California.
Q. Right.
A. That's right. With respect to IVC filters and filter monitoring. What confused me for a moment was your reference to Canada.
Q. Well, if you recall in that case, it was being proposed that Bard should sponsor a program where patients with Recovery and G2 filters should have a examination by a physician and radiographic tests to determine the position, condition of their devices. Do you recall that?
A. I do recall that there were issues on the subject of what would be appropriate monitoring for patients with those devices.
Q. And what do you think appropriate monitoring should be for patients with those devices?

24 A. I think that the first monitoring

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1 which is important is a clinical one; that is, a
2 physical exam and laboratory check and looking at
3 the patients to see if they have further evidence
4 of deep vein thrombosis which might mean impending
5 pulmonary embolus. The declaration itself dealt
6 with the issues of using repeated imaging such as
7 CT scans every year or every six months, and those
8 were some of the items that were discussed in that
9 particular subject.
10 Q. So you agree with the notion and
11 idea of patients being monitored who have a Bard
12 Recovery and G2 filter, it's just that your
13 program would be different than what was being
14 advocated by Dr. Ashe?
15 A. That would be fair to say. I agree
16 with monitoring and I agree with follow-up, but I
17 may not agree with some of the specific exact
18 details.

Deposition of Murray Asch, M.D., 1/5/2011, Kessler Report Footnote 88

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Q. At some point after you learned about the Recovery filter's problems with fracturing, and after your conversations with the Bard sales rep, do you remember attempting to communicate with Bard or John -- and/or John Kaufman through email or through correspondence about your concerns?
A. Yes. Initially I communicated with Bard, as I recall was on the telephone, further emphasizing my concerns about the device and following up on one of the recommendations made in one of the published articles where the recommendation was made that any physician who places the Bard Recovery filter should make all efforts to follow up, contact all their patients, radiograph them to identify a filter fracture before it led to an adverse clinical outcome. So based on that I contacted my Bard representative and I read them the article and said, "Hey, this is what that article says. You guys, this is your filter, I don't really have the resources in my community practice, can you please help me with lot numbers and

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dates, et cetera, go back and help my identify the patients and allow me to contact them so I can try and be sure that nothing bad happens?" And they said, "We don't really believe there's a problem with the filter and we don't have the time or ability to help you, so I'm sorry, we will not help you." So I was concerned about that so I contacted John Kaufman trying to figure out, you know, maybe I'm wrong here, maybe I'm making too big a deal of this. You know, there are many, in spite of the peer – quality of peer review journals that we discussed before, just because you read something in print doesn't make it necessarily right, and you know, we don't always alter our practice based on a single article we read. SO I contacted John trying to get a sense of some guidance, what should I do, and I expressed my frustration to him about Bard, and his repose echoed mine; that he was concerned about Bard's behavior – and I don't want to say too much about what he felt because he's not here to defend himself – but he did express his concern, share his concerns with me. And related to all those conversations, again that was all at the time that helped me decided that I should stop using the Bard product.

Schedule 12 - FDA and Bard Communications

Schedule 12 - FDA and Bard Communications

Date	Device	Summary
7/24/1989	SNF	NMT submits 510(k) application for SNF
4/20/1990	SNF	SNF filter cleared for market
4/16/1996	SNF	FDA clears Straight-line for SNF
11/4/1996	SNF	FDA denied SNF 510(k) application
1/13/1997	SNF	NMT submits 510(k) application for straight line SNF
2/11/1997	All	FDA's Design Control Guidance for Medical Device Manufacturer
3/20/1998	All	FDA's new requirements for abbreviated 510(k) process
9/2/1999	SNF	FDA clinical data summary of SNF
11/1/1999	SNF	NMT's Special 510(k) for modifications for SNF/SL system (renamed Recovery Filter)
12/10/1999	Recovery	FDA 510(k) Insufficiency Letter to market RNF
1/20/2000	Recovery	Letter re 2/10/00 FDA meeting with NMT to discuss Recovery
2/9/2000	Recovery	FDA meeting with NMT
2/29/2000	Recovery	NMT letter to FDA addressing concerns and suggesting a European clinical trial
0/0/2002	SNF/Recovery	Bard Peripheral Technologies and IMPRA combined to form Bard
7/11/2002	Recovery	Recovery 510(k) application (K022236) submission
8/5/2002	Recovery	FDA letter to Bard re 510(k) deficiencies
8/8/2002	Recovery	Responses to FDA questions
8/12/2002	Recovery	FDA teleconference
8/26/2002	Recovery	Email re draft responses to FDA Questions
8/30/2002	Recovery	Bard's formal response to FDA Questions re Recovery Filter
8/30/2002	Recovery	Letter from IMPRA (Bard Subsidiary) to FDA re K022236 and FDA's Aug. 5, 2002 questions
10/1/2002	Recovery	Teleconference with FDA to regarding deficiencies
10/3/2002	Recovery	Draft response for teleconference with FDA reviewers re Bard RNF response letter
10/4/2002	Recovery	Email and Letter from FDA to Bard re deficiencies
10/4/2002	Recovery	Responses needed to FDA questions re Recovery
10/25/2002	Recovery	Bard's Response to FDA Questions re Recovery Filter (K022236)
11/27/2002	Recovery	RNF cleared by FDA as a permanent device
11/27/2002	Recovery	Recovery Special 510(k) Submission (K022236)
11/27/2002	Recovery	Recovery Special 510(k) approval letter
12/17/2002	Recovery	Bard requests meeting with FDA re labeling and IFU
12/20/2002	Recovery	RNF launched in U.S.
3/14/2003	Recovery	FDA asked Bard to revise label to include indwell time

Schedule 12 - FDA and Bard Communications

4/25/2003	Recovery	Bard submits abbreviated 510(k) for Recovery (K022236)
7/1/2003	Recovery	FDA request "clinical experience" section for IFU
7/2/2003	Recovery	FDA email to Bard requesting clarification of animal and clinical testing
7/2/2003	Recovery	RNF cleared by FDA as an optional retrieval device
7/8/2003	Recovery	Bard sent FDA Recovery stability testing
7/23/2003	Recovery	Emails with FDA re abbreviated 510(k)
7/23/2003	Recovery	FDA requested 10 copies of Recovery IFU
7/24/2003	Recovery	Letter from Bard to FDA w/copies of revised IFU
7/25/2003	Recovery	Recovery abbreviated 510(k) FDA correspondence for removable device
2/12/2004	Recovery	Email from Edward re draft communications to the sales force re MAUDE database
9/17/2004	Recovery	Bard contacted local FDA office re intent to send Dear Doctor Letter
9/23/2004	Recovery	E-mail and final Dear Doctor Letter
9/28/2004	Recovery	FDA encouraging Dear Doctor Letter re adverse events and caval size
10/5/2004	Recovery	Bard responded to FDA questions re 510(k) (K031328)
10/9/2004	Recovery	Bard's CDRH Pre-Market Review Submission Cover Sheet
11/19/2004	Recovery	FDA letter re deficiencies in 510(k) (K031328)
11/29/2004	Recovery	Email with FDA's changes to Dear Doctor Letter re revised IFU
1/12/2005	Recovery	Fax to FDA with Recovery IFU and final Dear Doctor Letter informing changes to IFU
1/22/2005	Recovery	Email to FDA
1/25/2005	Recovery	Bard reports to FDA, adverse event rates remain the same or below SIR guidelines and will inform doctors that safety and effectiveness of prophylactic use of filters
1/27/2005	Recovery	Email, subject "Recovery communication with FDA"
2/4/2005	Recovery	FDA Contact Report; Shari Allen working on study for PMS registry
2/8/2005	Recovery	Fax to FDA answering questions about Dear Doctor Letter
2/8/2005	Recovery	FDA seeking additional info from Bard IFU for bariatric patients with permanent and removable filters
2/8/2005	Recovery	FDA requests information re K022236 and K031328
2/14/2005	Recovery	FDA requested U.S. adverse events, sales and complication table; FDA seeks info on Bard's plans to make device modifications to address migration and requested U.S. adverse events, sales and complication table
2/15/2005	Recovery	Email re 2/14/15 FDA Contact Report
2/21/2005	Recovery	Bariatric Surgeon Expert Panel Meeting in New Orleans
2/28/2005	Recovery	Bard response to FDA's 2/8/2005 request for additional information
3/2/2005	Recovery	Special 510(k) for K50558

Schedule 12 - FDA and Bard Communications

3/6/2005	Recovery	FDA didn't realize RNF did not have an upper limit indwell time
3/24/2005	Recovery & Modified Recovery (G2)	Recovery meeting with FDA agenda and minutes
3/28/2005	Modified Recovery (G2)	FDA review memo re Modified Recovery (G2) 510(k)
3/30/2005	Recovery	G1A special 510(k) FDA letter
4/19/2005	Recovery	Bard's Reponses to 03/30/05 FDA questions
4/26/2005	Recovery	Conference b/w Chris Sloan and Dave Buckles from Quintiles and FDA re K050558
4/27/2005	Recovery	Bard to FDA, seeking extension to answer FDA's March 30, 2005 questions
4/27/2005		FDA to Bard granting answer FDA's March 30, 2005 questions
5/2/2005	Recovery	Internal memo re Competitive Filter Data
5/2/2005	Modified Recovery (G2)	FDA review memo re animal study for Modified Recovery (G2) 510(k)
5/6/2005	Recovery	Teleconference with FDA to regarding deficiencies
5/11/2005	Recovery	Dear Colleague Letter
5/27/2005	Recovery	Teleconference with FDA to regarding deficiencies
6/3/2005	Recovery	Bard submits additional info to FDA re RNF design modifications
6/3/2005	Recovery	Email from Bard to FDA re proposed IDE
6/3/2005	Recovery	Bard's response to FDA's questions on 03/02/05
6/8/2005	Recovery	FDA request copy of Dear Colleague Letter
6/17/2005	Recovery	RE Special 510(K) converted to abbreviated 510(K)
6/24/2005	Recovery	FDA expressed concern about migrations and fractures
7/8/2005	Recovery	Recovery IDE application
7/26/2005	Recovery	FDA reviewer memo for Recovery 510(k)
7/26/2005	Recovery	FDA Contact Report
7/27/2005	Recovery	Emails with FDA re IDE application
7/28/2005	Recovery	FDA letter to Shari Allen
7/28/2005	Recovery	FDA Contact Report
8/8/2005	Modified Recovery (G2)	Email FDA Correspondence IDE
8/10/2005	Recovery	Bard's response to FDA's questions
8/16/2005	Recovery	FDA letter to Bard re IDE application (G050134)

Schedule 12 - FDA and Bard Communications

8/22/2005	Modified Recovery (G2)	Bard email to FDA enclosing revised IFU
8/22/2005	Recovery	FDA reviewer memo for Recovery 510(k)
8/25/2005	Modified Recovery (G2)	FDA Conference Call Meeting Minutes Recovery Filter System IDE (G050134)
8/26/2005	Modified Recovery (G2)	FDA adds "indication for use permanent" and "temporary use not established" language to Modified Recovery (G2) label
8/29/2005	Modified Recovery (G2)	Modified Recovery (G2) filtered cleared as permanent device
8/29/2005	Modified Recovery (G2)	Bard to include retrieval limiting statement on IFU and promotional material
8/30/2005	G3	Traditional 510(k) Modified Recovery (G2) filter - summary of safety and effectiveness (K050558)
9/1/2005	Recovery	RNF discontinued
9/5/2005	Recovery	MHRA concern re adverse event reports
10/13/2005	Recovery	FDA seeking additional info re changes to delivery system w respect to loading and deployment
10/14/2005	Modified Recovery (G2)	Modified Recovery (G2) 510(k) on hold until FDA receives additional info
11/25/2005	Modified Recovery (G2)	Modified Recovery (G2) cleared as an optional retrievable filter
12/6/2005	Recovery	Bards request for Recovery SR Pre-IDE meeting
1/5/2006	Modified Recovery (G2)	E-mail clinical update RA/CA monthly report - December 2005
2/13/2006	ALL	Dept. of Health and Human Services; Notice of Inspection
12/11/2006	Modified Recovery (G2)	E-mail with Summary of Remedial Actions
12/20/2006	Modified Recovery (G2)	Voluntary recall of Modified Recovery (G2) jugular 'Dear Hospital Administrator' letter
1/16/2007	Modified Recovery (G2)	Voluntary recall of Modified Recovery (G2) jugular follow-up
1/18/2007	Modified Recovery (G2)	Bard Establishment inspection Report

Schedule 12 - FDA and Bard Communications

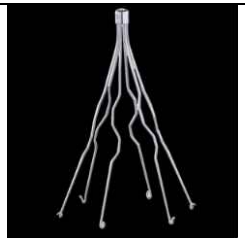
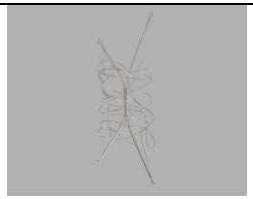
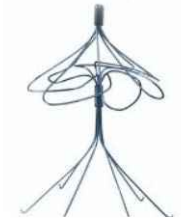
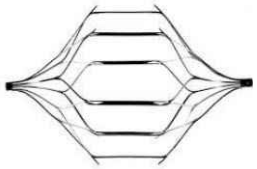
6/11/2007	Modified Recovery (G2)	Email - Sec 8.3.3 Relative Filter Movement
6/19/2007	Modified Recovery (G2)	Internal memo re Modified Recovery (G2) jugular recall summary and required FDA monthly status calls
7/5/2007	Modified Recovery (G2)	Letter to FDA to terminate Modified Recovery (G2) jugular recall
4/7/2008	Modified Recovery (G2)	Email re AER Chart Modified Recovery (G2) Filter information
5/5/2008	Modified Recovery (G2)	Bard requests extension to respond FDA questions re Modified Recovery (G2) Express
7/30/2008	G2X	G2X cleared for as permanent device
8/12/2008	G2X	Special 510(k) G2X Express Approval (K082305)
10/31/2008	G2X	G2X cleared for as an optional retrieval device
1/23/2009	All	Establishment of Inspection Report
11/25/2009	Eclipse	Bard submits Eclipse 510(k) application to FDA
12/17/2009	Eclipse	Bard's response to FDA Questions re Eclipse Femoral and Jugular (K093659)
1/7/2010	Eclipse	FDA Contact Report
1/7/2010	Eclipse	PPT shown to FDA at meeting
1/14/2010	Eclipse	Eclipse cleared for market use
2/3/2010	All	Filter FDA inspection preparation
2/24/2010	Modified Recovery (G2)	Filter FDA inspection preparation
5/20/2010	Eclipse	Special 510(k) Eclipse submission
8/9/2010	All	FDA Alert re removable filters
8/9/2010	All	FDA Alert re risk of adverse events in IVC filters
8/12/2010	All	Medical Article
8/31/2010	Meridian	Traditional 510(k) Meridian submission
11/18/2010	Meridian	FDA Contract Report- Meridian 510(k) response strategy meeting with FDA
8/18/2011	Modified Recovery (G2)	Medical Article (Clinical Study)
8/24/2011	Meridian	Meridian cleared for market use
8/24/2011	Meridian	510(k) Meridian Filter System- Femoral and Jugular/Subclavian Delivery Kits Approval
8/27/2011	Meridian	Special 510(k) Meridian submission

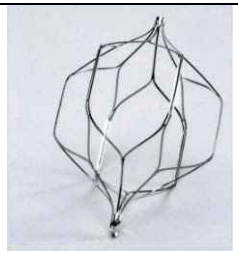
Schedule 12 - FDA and Bard Communications

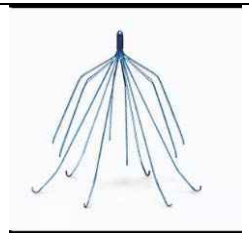
12/1/2011	Recovery	Medical Study Vena Cava Filter Fracture Unplanned Obsolescence
3/1/2012	Modified Recovery (G2), Modified Recovery (G2)X	Medical Article- Complex retrieval of fractured, embedded, and penetrating IVC filters a prospective study with histologic and electron microscopic analysis
2/13/2013	Denali	Bard submits 510(k) application for Denali
2/28/2013	Recovery, Modified Recovery (G2)	FDA concerned about adverse events
1/22/2015	Recovery	Response to FDA request for Dear Doctor Letter and formal survey for bariatric patients
3/4/2015	Recovery	Meeting with FDA re filters
3/20/2015	All	Dept. of Health and Human Services; Notice of inspection
7/17/2015	Eclipse	Cease Manufacturing of the Eclipse
7/17/2015 - 8/20/2015	Eclipse	Cease manufacturing of Eclipse

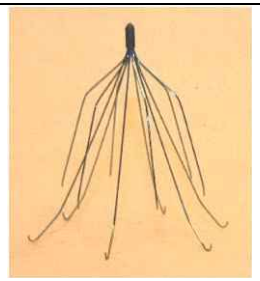
Schedule 13 – Diagrams and Intended Uses of IVC Filters

Schedule 13 – Diagrams and Intended Uses of IVC Filters

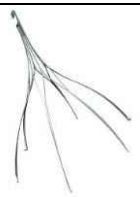
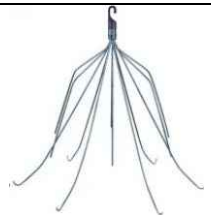
Filter	Image	Clearance	Indications for Use
Titanium Greenfield (Medi-Tech/ Boston Sci.)		4/9/87: Cleared Permanent (K870729)	
Bird's Nest (Cook)		4/26/89: Approved Permanent (PMA) (P850049) 7/22/16: Currently cleared as Gianturco-Roehm Bird's Nest Vena Cava Filter. (K161218) (Last supplement 2/3/06 (P850049/S009))	
Simon Nitinol (Nitinol/Bard)		4/20/90: Cleared Permanent (K894703) (Nitinol Medical Technologies, Inc.)	"The intended use ... is to prevent pulmonary embolisms from migrating to the pulmonary arteries." (K963016)
TrapEase (Cordis)		7/7/00: Cleared Permanent (K000062) (Nitinol Medical Technologies, Inc.)	

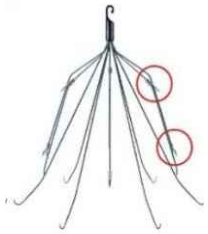
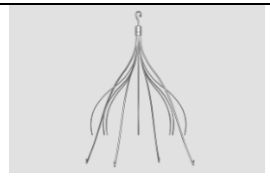
Gunther Tulip (Cook)		10/18/00: Cleared Permanent (K000855) Predicates: Boston Scientific Stainless Steel Greenfield Vena Cava Filter, B. Braun Medical (Vena Tech) LGM-Vena Tech 30 Series Filter 10/31/03: Cleared Optional (K032426) Predicates: Gunther Tulip Vena Cava Mreye Filter, Amplatz Goose Neck Snare Kit, Radius Microsnare	
Vena Tech LP (B. Braun)		5/18/01: Cleared Permanent (K010485)	
OptEase (Cordis)		10/18/02: Cleared Permanent (K023116) 3/22/04: Cleared Optional (K034050)	

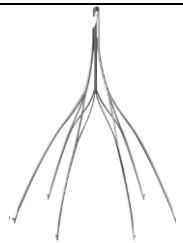
Bard Recovery		11/27/02: Cleared Permanent (K022236) Predicates: Simon Nitinol, Titanium Greenfield 7/25/03: Cleared Optional (K031328) Predicate: Recovery Filter System (K022236) 9/00/05: Discontinued	Permanent Indication for Use: "The Recovery Filter is indicated for use in the prevention of pulmonary embolism via placement in the vena cava in the following situations: • Pulmonary thromboembolism when anticoagulants are contraindicated. • Failure of anticoagulant therapy for thromboembolic disease. • Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced. • Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated." Optional Indication for Use: "The Recovery Filter System is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations: • Pulmonary thromboembolism when anticoagulants are contraindicated. • Failure of anticoagulant therapy for thromboembolic disease. • Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced. • Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated • Recovery filter may be removed according to the instructions supplied below under Section labeled: Optional Procedure for Filter Removal."

Bard G2		8/29/05: Cleared Permanent (K050558) Predicate: Recovery (K022236) 11/25/05: Cleared Subclavian Delivery Kit (K052578) Predicate: G2 Filter System Femoral Delivery Kit (K050558) 10/26/06: Cleared Delivery System (K062887) Predicate: G2 Filter System Femoral Delivery Kit (K050558) 1/15/08: Cleared Optional as "Recovery G2" (K073090) Predicate: G2 Filter System (K062887)	Permanent Indication for Use: "The G2 Filter System is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations: • Pulmonary thromboembolism when anticoagulants are contraindicated. • Failure of anticoagulant therapy for thromboembolic disease. • Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced. • Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated." Retrievable Indication for Use: "The G2 Filter System is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations: • Pulmonary thromboembolism when anticoagulants are contraindicated. • Failure of anticoagulant therapy for thromboembolic disease. • Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced. • Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated • Recovery filter may be removed according to the instructions supplied below under Section labeled: Optional Procedure for Filter Removal."

Celect (Cook)		4/20/07: Cleared Permanent (K061815) Predicate: Gunther Tulip (K000855) 3/7/08: Cleared Optional (K073374) Predicates: Celect (K061805)(filter), Gunther Tulip Vena Cava Filter Retrieval Set (K032426) (retrieval device)	2007: "The Cook Celect Vena Cava Filter is intended for the prevention of recurrent pulmonary embolism (PE) via placement in the vena cava...."
ALN Optional (ALN)		1/30/08: Cleared Optional (K070514) Predicates: Greenfield (K912035), Recovery Cone Removal System (K031328)	
Bard G2 Express		7/30/08: Cleared Optional (K080668) Predicate: Recovery G2 (K073090) 10/31/08: Cleared Delivery Kits (K082305) Predicate: G2 Express (K080668) 4/28/10: Discontinued (BPVE-01-00761124)	"The G2 X Vena Cava Filter is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations: • Pulmonary thromboembolism when anticoagulants are contraindicated. • Failure of anticoagulant therapy for thromboembolic disease. • Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced. • Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated. • G2 X Filter may be removed according to the instructions supplied below under Section labeled: Optional Procedure for Filter Removal."

Option (Rex Medical)		6/4/09: Cleared Optional (K081410) Predicates: Greenfield (K964284), Optease (K023116), Trapease (K000062), Recovery (K022236), G2 (K073090), Gunther Tulip (K032426)	"The Option Vena Cava Filter is intended for the prevention of recurrent pulmonary embolism (PE) via placement in the vena cava...."
Bard Eclipse		1/14/10: Cleared Optional (K093659) Predicate: G2 Express (K082305) 6/25/10: Cleared Brochure/Card (K101431) 7/7/15: Placed on hold (BPV-17-01-206982)	"The Eclipse Filter is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations: • Pulmonary thromboembolism when anticoagulants are contraindicated. • Failure of anticoagulant therapy for thromboembolic disease. • Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced. • Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated. • Eclipse Filter may be removed according to the instructions supplied below under Section labeled: Optional Procedure for Filter Removal."

Bard Meridian		8/24/11: Cleared Optional (K102511) Predicate: Eclipse (K101431) 7/17/15: Manufacturing ceased in July/August 2014 and remaining inventory was placed on hold July 17, 2015. (BPV-17-01-00223935)	"The Meridian Filter is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations: • Pulmonary thromboembolism when anticoagulants are contraindicated. • Failure of anticoagulant therapy for thromboembolic disease. • Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced. • Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated. Meridian Filter may be removed according to the instructions supplied under Section labeled: Optional Procedure for Filter Removal."
Celect Platinum (Cook)		7/3/12: Cleared Optional (K121629) Predicate: Celect (K073374, K090140, K121057)	"Compared to the predicate devices, the Cook Celect Platinum Vena Cava Filter Sets have identical indications for use, the same fundamental technological characteristics, and similar materials of construction.... The radiopaque marker on each primary leg is constructed from a platinum tungsten alloy; the radiopaque markers enhance filter visibility on procedural imaging."
ALN Optional (ALN)		11/9/12: Cleared Optional (K113124) Predicates: Greenfield (K912035), Recovery Cone Removal System ALN Optional (K070514)	

Bard Denali		5/15/13 Cleared Optional (K130366) Predicate: Eclipse (K101431)	
Option Elite (Rex Medical)		12/17/13: Cleared Optional (K133243) Predicate: Option (K081410)	"The Option ELITE consists of 6 small retention hooks identical to the Option small retention hooks compared to the Option that has 3 small retention hooks and 3 large retention hooks. 3 small retention hooks provide an equal contribution to the retention force and stability as the 3 large retention hooks. Changing to a filter that has 6 small retention hooks instead of 3 small and 3 large retention hooks will allow a lower profile filter without any new issues of safety and efficacy."
Vena Tech Convertible (B. Braun)		2/26/16: Cleared Permanent. (K152765)	

Schedule 14 – Bard Communications to Doctors

Schedule 14 - Bard Communications to Doctors

Date	Device	Summary	Bates
9/23/2004	Recovery	Bard finalized and approved a “Dear Doctor” letter. Shortly after, Bard distributed that letter, which “[a]ttached the latest version of the Information for Use” and set forth “key points from [Bard’s] revised IFU” including: “Movement or migration of the filter is a known complication of vena cava filters" and Filter fracture is a known complication of vena cava filters.”	BPVE-01-00303515
5/11/2005	Recovery	John McDermott, BPV President, and David Ciavarella, C.R. Bard Staff Vice President of Corporate Clinical Affairs, sent a second “Dear Doctor” letter with the stated purpose of updating physicians on Bard’s “internal analysis of reported adverse events related to the Recovery® Filter,” which included a statement that “Movement or migration is a known complication of vena cava filters.”	BPVE-DEP-00004822
12/20/2006	G2	Voluntary recall of G2 Filter- Jugular 'Dear Hospital Administrator' letter advising hospitals of recall due to "three complaints for the device that involve reports of introducer sheath tip damage."	BPV-17-01-00127807

IMPORTANT: INFORMATION FOR USE UPDATE

DEAR DOCTOR:

Attached is the latest version of the Information for Use (IFU) for the Recovery® Filter System from Bard Peripheral Vascular, Inc. Please take time to read this document in its entirety.

After 18 months of product availability, we have gained valuable clinical information about the usage of our product. In addition, we have reviewed the current literature, compared our labeling to that in use for other IVC filters, and consulted with experts in the field of thromboembolic disease treatment and prevention (interventional radiology, hematology, general internal medicine, vascular medicine, and the following surgical disciplines: vascular, trauma, and general surgery). Based on this information, we have revised the Recovery Filter System IFU to reflect what we believe are best practices and to highlight important warnings and precautions.

Following are key points from our revised IFU. In brief, we wish to reemphasize the following patient selection, procedure and device information:

Under Warnings:
The following information has been added:

- Do not deploy the filter unless IVC has been properly measured. (Refer to Point #2 – **Under Precautions**).
- Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in cardiopulmonary symptoms some of which have led to retrieval of the filter fragment through open-heart surgery or other invasive procedures. Most cases of filter fracture, both those reported through adverse event reporting and in the published literature, have been reported without clinical consequence.
- Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs has been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.

Under Precautions:
The following information has been added:

- Position the filter tip 1 cm below the lowest renal vein. Venacavography must always be performed to confirm proper implant site. Radiographs without contrast, which do not clearly show the wall of the IVC, may be misleading.
- When measuring caval dimensions, consider an angiographic catheter or Intravascular Ultrasound (IVUS) if there is any question about caval morphology.
- If misplacement or sub-optimal placement of the filter occurs, consider immediate retrieval. Retrieve the ***Recovery*** Filter using the ***Recovery Cone*** Removal System only. Refer to the Optional Procedure for Filter Removal section for details.
- In patients with continued risk of chronic, recurrent pulmonary embolism, patients should be returned to anti-thrombotic therapy as soon as it is deemed safe.
- If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and use the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.
- The introducer catheter has radiopaque markers to assist in visualization and predeployment filter positioning. The radiopaque markers on the introducer catheter provide a "target" location between which the filter should be positioned just prior to unsheathing and deployment.
- The introducer catheter hub has a special internal design. Care should be taken to make connections firmly, but without excessive force that may cause breakage of the hub.
- It is very important to maintain introducer catheter patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become covered by clot. This will interfere with filter deployment.
- Do not deliver the filter by pushing it beyond the end of the introducer catheter. To achieve proper placement, unsheath the stationary filter by withdrawing the introducer catheter.

Under Potential Complications:
After reviewing other IVC manufacturer IFUs, the following information was rewritten as follows:
Procedures requiring percutaneous interventional techniques should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure.
Possible complications include, but are not limited to, the following:

- Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs has been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.
- Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in cardiopulmonary symptoms some of which have led to retrieval of the filter fragment through open-heart surgery or other invasive procedures. Most cases of filter fracture, both those reported through adverse event reporting and in the published literature, have been reported without clinical consequence.
- Perforation or other acute or chronic damage of the IVC wall.
- Acute or recurrent pulmonary embolism. This has been reported despite filter usage. It is not known if thrombi passed through the filter, or originated from superior or collateral vessels.
- Caval thrombosis/occlusion.
- Extravasation of contrast material at time of venacavogram.
- Air embolism.
- Hematoma or nerve injury at the puncture site or subsequent retrieval site.
- Hemorrhage.
- Restriction of blood flow.
- Occlusion of small vessels.
- Distal embolization.
- Infection.
- Intimal tear.
- Stenosis at implant site.

All of the above complications have been associated with serious adverse events such as medical intervention and/or death. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

We hope this information is helpful to you and your patients in using the Recovery Filter System. Should you have any questions on the enclosed Instructions for Use, please contact your Territory Manager or our Medical Services and Support department at 1-800-562-0027.

Regards,

Janet Hudnall
Marketing Manager
Vena Cava Filters

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May 11, 2005

Dear Colleague:

The purpose of this letter is to update you on Bard Peripheral Vascular's (BPV's) internal analysis of reported adverse events related to the Recovery® filter. Since the introduction of the Recovery vena cava filter in the United States in December 2002, we estimate that over 20,000 patients have benefited from receiving a Recovery filter. Over the past two years, we have received adverse event reports of filter migration, some being associated with medical intervention and/or death. Our overall migration-related fatality rate is below the reported (0.1%) and threshold (1.0%) rates, as described in the Society for Interventional Radiologists' *Quality Improvement Guidelines*[1]. We have determined that the majority of these migration-related fatalities have been associated with the use of the Recovery filter in morbidly obese patients.

Even though we have conducted a comprehensive investigation into each of the reported events, we have been unable to fully understand the etiology, including any association with prophylactic placement. BPV continues to analyze available published literature on vena cava filters and is conducting formal research to better understand the morbidly obese patient population. Physicians have indicated that there is a significant need to allow an IVC Filter to remain in place for an extended period of time (> 30 days) in certain high risk patient populations, including morbidly obese patients. In addition, the extended removability of the Recovery filter is an important clinical feature when compared with other commercially available filters.

What You Should Do

1. **Follow the Instructions for Use (IFU)**
   The risk/benefit ratio of the Recovery filter system should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention. If you determine that Recovery filter placement is warranted, we strongly advise you to use the Recovery filter in accordance with the Instructions for Use (IFU). In particular, note the following key points from our IFU.

   Indications for Use

   The Recovery Filter System is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:
   - Pulmonary thromboembolism when anticoagulants are contraindicated.
   - Failure of anticoagulant therapy for thromboembolic disease.

[1] Grassi CJ, Swan TL, Cardella JF et al: Quality Improvement guidelines for percutaneous permanent inferior vena cava filter placement for the prevention of pulmonary embolism. J Vasc Interv Radiol 2003; 14:S271-S275.

- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.
- Recovery filter may be removed according to the IFU Section labeled: Optional Procedure for Filter Removal.

Contraindications

The Recovery filter **should not** be implanted in:
- Pregnant patients when fluoroscopy may endanger the fetus. Risks and benefits should be assessed carefully.
- **Patients with an IVC diameter larger than 28 mm.**
- Patients with risk of septic embolism.

Sizing:
The IFU also states, **"The Recovery filter should not be deployed unless the IVC has been properly measured (≤ 28 mm)"** (note also that physicians have indicated that it is difficult to measure the IVCs of morbidly obese patients due to size/weight limits on standard angiography tables and CT scanners. However, every effort should be made to ensure that the IVC is measured accurately and that it is of appropriate size). You should also consider the following important points from our IFU:
- If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter through it as migration of the clot and/or filter may occur. Attempt filter delivery through an alternate site.
- **Movement or migration is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding 28 mm.**
- Migration of filters to the heart or lungs have been reported in association with improper deployment, deployment into clots and/or dislodgement due to large clot burdens.
- When measuring caval dimensions, consider an angiographic catheter or IntraVascular Ultrasound (IVUS) if there is any question about caval morphology.
- If misplacement or sub-optimal placement of the filter occurs, consider immediate retrieval. Retrieve the Recovery Filter using the Recovery Cone Removal System only.

Anticoagulation Regimen

In patients with continued risk of chronic, recurrent pulmonary embolism, patients should be returned to anticoagulant therapy as soon as it is deemed safe.

2. **Report Your Experience**
   In most medical devices, rare complications and their risks for specific populations are difficult to detect. Therefore, as a matter of course, it is important for you to report any product complaints and adverse events directly to BPV by:
   - **Telephone to BPV Field Assurance** at 1-800-321-4254 x2603

   Further, you should follow the reporting procedures established by your facility in accordance with the Safe Medical Devices Act of 1990 (SMDA), which requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices. You may also report adverse events directly to FDA/MedWatch by:
   - **Telephone** at 1-800-FDA-1088 (1-800-332-1088)
   - **Fax** at 1-800-FDA-0178 (1-800-332-0178)
   - **Online** at www.fda.gov/MedWatch
   - **Mail** your postage paid MedWatch form to the address provided on the form

For more information, visit the MedWatch website at www.fda.gov/MedWatch.

Bard is deeply committed to patient safety and to obtaining a better understanding of the risk/benefit of the Recovery filter in morbidly obese patients. We will continue to investigate all adverse events and conduct additional market and clinical research to provide you with important information to provide the best care for your patients.

Regards,

John McDermott
President
Bard Peripheral Vascular, Inc.

David Ciavarella, MD
Staff Vice President, Corporate Clinical Affairs
C. R. Bard, Inc.

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URGENT PRODUCT RECALL NOTIFICATION

December 20, 2006

Dear Hospital Administrator:

Please be advised that, effective immediately, Bard Peripheral Vascular, Inc. (BPV) is conducting a voluntary product recall on the G2™ Filter System – Jugular/Subclavian Delivery Kit, catalog number RF-320J. This action is being taken because BPV has recently received three complaints for the device that involve reports of introducer sheath tip damage. The damage may result in loss of tip integrity.

To date, there have been no patient injuries related to this issue; however, the damaged tip presents the potential to injure the vein wall or lead to tip fragment embolization.

Our records indicate that product affected by the recall has been shipped to your facility. **It is important that any G2™ Filter System – Jugular/Subclavian Delivery Kit devices with the catalog number RF-320J be immediately removed from your inventory and isolated from use.** Please share this information with physicians that perform these procedures at your facility.

Once the product affected by the recall has been removed from your inventory, please contact the BPV Recall Coordinator, Kim Stock, by calling 1.800.321.4254 x2766 or e-mailing at Kim.Stock@crbard.com to obtain a Return Authorization (RCL) Number. This will facilitate replacement for the returned devices.

A mailing label is enclosed for your convenience to return the recalled product. Please identify the package as "RECALLED PRODUCT" and include the RCL number. All products should be returned to the following shipping address:

Bard Peripheral Vascular, Inc.
1415 W. 3rd Street
Tempe, AZ 85281

Please complete the enclosed Recall and Effectiveness Check Form and fax to the attention of Kim Stock in Customer Service at 1.800.440.5376, even if you no longer have possession of the recalled product.

Any adverse reactions experienced with the use of this product, and/or quality problems should be reported to Bard Peripheral Vascular, Inc. by calling 1.800.321.4254 x 2560 and to the FDA's MedWatch Program by phone at 1.800.FDA.1088, by fax at 1.800.FDA.0178, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch Web site at www.fda.gov/medwatch.

1625 West 3rd Street • P. O. Box 1740 • Tempe, AZ 85280-1740
Tel: 1-800-321-4254 • 1-480-894-9515 • Fax: 1-480-966-7062 • www.bardpv.com

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We appreciate your cooperation and assistance in dealing with this matter and sincerely apologize for any inconvenience that may result from this action.

Sincerely,

John McDermott
President
Bard Peripheral Vascular, Inc.

G2™ Filter System is a trademark of C.R. Bard Inc., or an affiliate.

1625 West 3rd Street • P. O. Box 1740 • Tempe, AZ 85280-1740
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RECALL AND EFFECTIVENESS CHECK FORM

G2™ Filter System – Jugular/Subclavian Delivery Kit

All G2™ Filter System – Jugular/Subclavian Delivery Kit products with the RF-320J catalog number are affected by this recall.

It is important that the products with the catalog number RF-320J are immediately removed from your inventory and isolated from use.

Please complete this form as soon as possible and fax to 1-800-440-5376.

1. Did you receive notification that the affected product is being recalled?

   Yes_____ No_____

2. Did you receive shipments of the affected product being recalled? If no, please complete the contact information below and return the form as soon as possible.

   Yes_____ No_____

3. Do you currently possess any of the affected product? (*Please check both consignment and purchased inventory for possible locations of this affected product.*)

   Yes_____ No_____

4. If the answer to question 3 is YES, do you intend to return the affected product as requested?

   Yes_____ No_____

   If Yes, Total # of Pieces: _____

5. If the answer to question 4 is NO, please explain why?

_____

_____

Please PRINT Your Contact Information:

Name:_____ Title:_____

Name of Account/Hospital:_____

Date:_____

Phone #:_____

Please Fax completed form to: **Fax: 1-800-440-5376** **Attn: Kim Stock**
Customer Service
Bard Peripheral Vascular, Inc.

1625 West 3rd Street • P. O. Box 1740 • Tempe, AZ 85280-1740
Tel: 1-800-321-4254 • 1-480-894-9515 • Fax: 1-480-966-7062 • www.bardpv.com

Schedule 15 - List of Alternatives to IVC filters

Schedule 15 - List of Alternatives to IVC filters

Medications/Treatments	Types	Indications	Mechanism of Action	Adverse Effects
Apixaban[1-6,23]	Oral direct factor Xa inhibitor	Prevention and treatment of venous thromboembolism, thromboprophylaxis for atrial fibrillation	Direct factor Xa inhibitor	Bleeding
Argatroban[7]	Direct thrombin inhibitor	Treatment of heparin induced thrombocytopenia (HIT), percutaneous coronary interventions and coronary thrombosis in HIT	Binds to and inactivates thrombin	Bleeding
Bivalirudin[7]	Direct thrombin inhibitor	Treatment of heparin induced thrombocytopenia (HIT), percutaneous coronary interventions and coronary thrombosis in HIT	Binds to and inactivates thrombin	Bleeding
Dabigatran[8-11,23-24]	Oral direct thrombin inhibitor	Prevention and treatment of venous thromboembolism, thromboprophylaxis for atrial fibrillation	Direct thrombin inhibitor	Bleeding
Dalteparin[12,13,23-26]	Low Molecular Weight Heparin	Prevention of venous thromboembolism in hospitalized medical and surgical patients, treatment of VTE in cancer patients, treatment of VTE	Binds to and accelerates inactivation of activated forms of factors X>II by antithrombin	Bleeding, lower risk of HIT, osteoporosis
Edoxaban[14,15,23]	Oral direct factor Xa	Prevention and treatment of	Direct factor Xa inhibitor	Bleeding

Medications/Treatments	Types	Indications	Mechanism of Action	Adverse Effects
	inhibitor	venous thromboembolism, thromboprophylaxis for atrial fibrillation		
Enoxaparin[16,23-26]	Low Molecular Weight Heparin	Prevention and treatment of venous thromboembolism, acute thromboprophylaxis for atrial fibrillation, acute thromboprophylaxis for mechanical and bioprosthetic heart valves, prevention of arterial thromboembolism in patients with coronary artery disease undergoing percutaneous coronary interventions	Binds to and accelerates inactivation of activated forms of factors X>II by antithrombin	Bleeding, lower risk of HIT, osteoporosis
Fondaparinux[16,17,23-26]	Indirect factor Xa inhibitor	Prevention and treatment of venous thromboembolism,	Indirect factor Xa inhibitor;Binds to and accelerates inactivation of factors Xa by antithrombin	Bleeding
Intermittent pneumatic compression devices (Sequential compression devices)[18,19]	Mechanical compression therapy	Prevention of VTE	Mechanical compression of veins prevents venous stasis, promotes local secretion of tissue plasminogen activator	Skin ulceration
Rivaroxaban[20-24]	Oral direct factor Xa inhibitor	Prevention and treatment of venous thromboembolism, thromboprophylaxis for	Direct factor Xa inhibitor	Bleeding

Medications/Treatments	Types	Indications	Mechanism of Action	Adverse Effects
		atrial fibrillation		
Unfractionated Heparin[23-26]	Heparin	Prevention and treatment of venous thromboembolism, acute thromboprophylaxis for atrial fibrillation, acute thromboprophylaxis for mechanical and bioprosthetic heart valves, prevention of arterial thromboembolism in patients with coronary artery disease undergoing percutaneous coronary interventions	Binds to and accelerates inactivation of activated forms of factors II and X by antithrombin	Bleeding, heparin induced thrombocytopenia (HIT), osteoporosis
Warfarin (e.g., Coumadin)[23,24]	Vitamin K antagonist	Prevention and treatment of venous thromboembolism, thromboprophylaxis for atrial fibrillation, thromboprophylaxis for mechanical and bioprosthetic heart valves	Inhibits vitamin K epoxide reductase resulting in acquired deficiency of vitasmin K dependent coagulation factors 2,7,9,10	Bleeding, warfarin-induced skin necrosis, hair loss

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Schedule 16 - FDA Communications to Doctors

Schedule 16 - FDA Communication to Doctors

Date	Device	Summary	Source
8/9/2010	All	FDA communicates a concern reagrding the risk of adverse events in IVC filters, including long-term filter use for retrievable IVC filters intended for short-term placement. FDA recommends removal of filter once a patient's risk for PE subsides.	BPV-17-01-001441621
5/6/2014	All	The FDA recommends that implanting physicians and clinicians responsible for the ongoing care of patients with retrievable IVC filters consider removing the filter as soon as protection from pulmonary embolism is no longer needed.	http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm396377.htm

U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration

Medical Devices

Removing Retrievable Inferior Vena Cava Filters: Initial Communication

Date Issued: August 09, 2010
Audience: For implanting physicians and clinicians responsible for the ongoing care of patients with inferior vena cava (IVC) filters. Includes interventional radiologists, interventional cardiologists, vascular surgeons, emergency room physicians (trauma), bariatric surgeons, orthopedic surgeons, primary care physicians

Device:
IVC filters are small, cage-like devices that are inserted into the inferior vena cava (the main vessel returning blood from the lower half of the body to the heart) to capture blood clots and prevent them from reaching the lungs. IVC filters are frequently placed in patients at risk for pulmonary embolism (a blood clot in the lungs) when anticoagulant therapy cannot be used or is ineffective. Some patients may require long-term protection from PE, and implantation of permanent IVC filters is often performed in these cases. Others only require short-term protection, in which case retrievable IVC filters are typically used, as these devices have the option to be removed once the patient's risk of PE subsides.

Summary of Problem and Scope:

IVC filter usage has increased rapidly during the past thirty years. In 1979, 2,000 IVC filters were used, while in 2007, almost 167,000 filters were implanted, and the market for IVC filters is only expected to increase, with an estimated 259,000 IVC filters to be deployed in 2012 (Smouse and Kohar, *Endovascular Today*, February 2010).

Since 2005, the FDA has received 921 device adverse event reports involving IVC filters, of which 328 involved device migration, 146 involved embolizations (detachment of device components), 70 involved perforation of the IVC, and 56 involved filter fracture. Some of these events led to adverse clinical outcomes in patients. These types of events may be related to a retrievable filter remaining in the body for long periods of time, beyond the time when the risk of PE has subsided.

The FDA is concerned that these retrievable IVC filters, intended for short-term placement, are not always removed once a patient's risk for PE subsides. Known long term risks associated with IVC filters include but are not limited to lower limb deep vein thrombosis (DVT), filter fracture, filter migration, filter embolization and IVC perforation.

Recommendations/Actions:

FDA recommends that implanting physicians and clinicians responsible for the ongoing care of patients with retrievable IVC filters consider removing the filter as soon as protection from PE is no longer needed.

FDA encourages all physicians involved in the treatment and follow-up of IVC filter recipients to consider the risks and benefits of filter removal for each patient. If a patient has a retrievable IVC filter that should be removed based on his or her individual risk/benefit profile, the primary care physician and/or those providing ongoing patient care should refer the patient for IVC filter removal when feasible and clinically indicated.

FDA Activities:

This initial communication is in keeping with FDA's commitment to inform the public about emerging device safety issues. The Agency will communicate its final conclusions when the analysis of available data is complete.

As part of developing our final position, FDA reviewed the literature and is conducting quantitative decision analysis modeling to evaluate the change in the risk/benefit profile after retrievable IVC filter implantation over time. More information about FDA's decision analysis model including risk/benefit implantation timeframe suggestions will be made available in an update to this communication as well as in a future publication in a peer-reviewed medical journal.

Contact Information:
If you have questions about this communication, please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at DSMICA@cdrh.fda.gov or 800-638-2041.
This document reflects FDA's current analysis of available information, in keeping with our commitment to inform the public about ongoing safety reviews of medical devices.

Links on this page:

Removing Retrievable Inferior Vena Cava Filters: FDA Safety Communication

This safety communication updates FDA's 2010 Initial Communication. The update provides information on recently published research and postmarket studies for these devices. There are no new safety concerns related to this update.

Date Updated: May 6, 2014

Date of Initial Communication: August 9, 2010 (/MedicalDevices/Safety/AlertsandNotices/ucm221676.htm)

Audience: Physicians who implant inferior vena cava (IVC) filters and clinicians responsible for the ongoing care of patients with these devices.

Medical Specialties: Interventional radiology, interventional cardiology, vascular surgery, trauma care, bariatric surgery, orthopedic surgery, primary care

Device:
IVC filters are small, cage-like devices that are inserted into the inferior vena cava to capture blood clots and prevent them from reaching the lungs. The inferior vena cava is the main vessel returning blood from the lower half of the body to the heart. IVC filters are frequently placed in patients at risk for pulmonary embolism (a blood clot in the lungs) when anticoagulant therapy cannot be used or is ineffective. IVC filters are designed to be permanent implants although some of these devices may have the option to be removed.

Purpose: The Food and Drug Administration (FDA) is updating a previously issued Initial Communication to include information on recently published research and postmarket surveillance studies for these devices.

Summary of Problem and Scope:
The FDA has received reports of adverse events and product problems associated with IVC filters. Types of reports include device migration, filter fracture, embolization (movement of the entire filter or fracture fragments to the heart or lungs), perforation of the IVC, and difficulty removing the device. Some of these events led to adverse clinical outcomes. These types of events may be related to how long the filter has been implanted. Other known long-term risks associated with IVC filters include lower limb deep vein thrombosis and IVC occlusion. For patients with retrievable filters, some complications may be avoided if the filter can be removed once the risk of pulmonary embolism has subsided. The FDA is concerned that retrievable IVC filters, when placed for a short-term risk of pulmonary embolism, are not always removed once the risk subsides.

Recommendations/Actions:
The FDA recommends that implanting physicians and clinicians responsible for the ongoing care of patients with retrievable IVC filters consider removing the filter as soon as protection from pulmonary embolism is no longer needed.

The FDA encourages all physicians involved in the treatment and follow-up of patients receiving IVC filters to consider the risks and benefits of filter removal for each patient. A patient should be referred for IVC filter removal when the risk/benefit profile favors removal and the procedure is feasible given the patient's health status.

FDA Activities:
The FDA developed a quantitative decision analysis using publicly available data available in the medical literature to assess whether there is a time period during which the risk of having an IVC filter in place is expected to outweigh the benefits. The decision analysis (Decision Analysis of Retrievable Inferior Vena Cava Filters in Patients without Pulmonary Embolism) was published in the **Journal of Vascular Surgery: Venous and Lymphatic Disorders (/downloads/MedicalDevices/Safety/AlertsandNotices/UCM396384.pdf)** in October 2013. The mathematical model suggested that if the patient's transient risk for pulmonary embolism has passed, the risk/benefit profile begins to favor removal of the IVC filter between 29 and 54 days after implantation.

Although the results of the decision analysis provide important insight for retrievable IVC filters, the FDA is requiring collection of additional clinical data for currently marketed IVC filters in the United States. The studies will address safety questions that remain unanswered for both permanent and retrievable filters. Manufacturers were given two options for obtaining the data. Some manufacturers are participating in the **PRESERVE (http://evtoday.com/2012/10/preserve-trial-to-be-a-comprehensive-study-of-inferior-vena-cava-filters)** (PREdicting the Safety and Effectiveness of InferioR VEna Cava Filters) study, an independent national clinical study that will examine the use of IVC filters in the prevention of pulmonary embolism. Other manufacturers are conducting postmarket surveillance (**522 Studies (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pss.cfm)**). The data gathered from the PRESERVE study and the 522 studies will help the FDA, manufacturers and health care professionals assess the use and safety profile of these devices, understand evolving patterns of clinical use of IVC filters and ultimately improve patients care.

Contact Information:
If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at **DICE@cdrh.fda.gov (mailto:DICE@cdrh.fda.gov)** or 800-638-2041.

Resources

- **Decision Analysis of Retrievable Inferior Vena Cava Filters in Patients without Pulmonary Embolism (PDF - 553KB) (/downloads/MedicalDevices/Safety/AlertsandNotices/UCM396384.pdf)**
- **Decision Analysis of Retrievable Inferior Vena Cava Filters in Patients Without Pulmonary Embolism (Abstract) (http://www.jvsvenous.org/article/S2213-333X(13)00051-6/abstract) (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**
- **522 Postmarket Surveillance Studies (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm)**
- **PRESERVE Study to be Comprehensive Evaluation of Inferior Vena Cava Filter Use (Endovascular Today) (http://evtoday.com/2012/10/preserve-trial-to-be-a-comprehensive-study-of-inferior-vena-cava-filters) (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**

More in Safety Communications (/MedicalDevices/Safety/AlertsandNotices/default.htm)

Information About Heparin (/MedicalDevices/Safety/AlertsandNotices/ucm135345.htm)

Preventing Tubing and Luer Misconnections (/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm)

Schedule 17 – SIR Guidelines – Analysis of Filters Referenced in Supporting Articles

Schedule 17- SIR Guidelines – Analysis of Filters Referenced in Supporting Articles

2003 SIR Guidelines
Table 2: Perforation, Migration, Fracture Events

Footnote	Article Title	Filter(s) Referenced
7	Inferior vena cava filters: indication, safety, effectiveness. 1992.	Greenfield Medi-Tech, Bird's Nest, LGM (Vena-Tech), Titanium Greenfield, SNF, Gunther, Amplatz, Modified Greenfield
9	Inferior Vena Caval Filters: Analysis of Five Currently Available Devices. 1990.	Greenfield Stainless Steel Filter, Bird's Nest, Titanium Greenfield Filter, Vena-Tech Filter, SNF
10	Percutaneous inferior vena caval filters. 1990.	Greenfield Stainless Steel, Bird's Nest, LGM (Vena-Tech), SNF, Titanium Greenfield, Amplatz, Gunther
17	Percutaneous Inferior vena caval filters: follow-up of seven designs in 320 patients. 1993.	Birds Nest Type I, Birds Nest Type II, Amplatz, Nitinol, Titanium Greenfield, Titanium modified hook design, Vena-Tech
19	LGM (Vena-Tech) Vena Caval Filter: Experience at a Single Institution. 1994.	LGM (Vena-Tech), Stainless Steel Greenfield, Titanium Greenfield, Bird's Nest, Nitinol
20	Vena Tech-LGM Filter: Long-term Results of a Prospective Study. 1993	LGM (Vena-Tech)
21	Simon Nitinol Inferior Vena Cava Filter: Initial Clinical Experience. 1989	SNF
23	Current Use of Inferior Vena Cava Filters. 1992	Bird's Nest, Greenfield, Vena-Tech
24	Complications of the Nitinol Vena Caval Filter. 1992.	SNF
26	Percutaneous Transvenous Caval Interruption with "LGM" Filter: Early Results of a Multicenter Trial. 1988	LGM (Vena-Tech), Greenfield, Combe
27	Results of long-term venacavography study after placement of a Greenfield vena caval filter. 1992	Greenfield SGF, Greenfield, TGF, LGM (Vena-Tech)
40	Complications of Vena Cava Filters. 1993	Mobin-Uddin umbrella, Kimray-Greenfield stainless-steel filter, Bird's Nest, Greenfield Titanium, Simon Nitinol, Vena-Tech Filter.
41	LGM Vena Cava Filter: Objective Evaluation of Early Results. 1991	LGM (Vena-Tech), Greenfield
42	Technical Problems and Complications Associated with Inferior Vena Cava Filters. 1994.	Titanium Greenfield, Bird's Nest, Vena-Tech, SNF.
52	Vena Cava Filters: Prevalent	No specific filter(s) identified.

	Misconceptions. 1999.	

2011 SIR Guidelines
Table 2: Perforation, Migration, Fracture Events

Footnote	Article Title	Filter(s) Referenced
7	Inferior vena cava filters: indication, safety, effectiveness. 1992.	Greenfield Medi-Tech, Bird's Nest, LGM (Vena-Tech), Titanium Greenfield, SNF, Gunther, Amplatz, Modified Greenfield
10	Percutaneous inferior vena caval filters. 1990.	Greenfield Stainless Steel, Bird's Nest, LGM (Vena-Tech), SNF, Titanium Greenfield, Amplatz, Gunther
12	Inferior Vena Caval Filters: Analysis of Five Currently Available Devices. 1990.	Greenfield Stainless Steel Filter, Bird's Nest, Titanium Greenfield Filter, Vena-Tech Filter, SNF
24	Percutaneous Inferior vena caval filters: follow-up of seven designs in 320 patients. 1993.	Birds Nest Type I, Birds Nest Type II, Amplatz, Nitinol, Titanium Greenfield, Titanium modified hook design, Vena-Tech
43	Current Use of Inferior Vena Cava Filters. 1992	Bird's Nest, Greenfield, Vena-Tech
55	Results of a multicenter study of the modified hook-titanium Greenfield filter. 1991.	Titanium Greenfield Filter, Stainless Steel Greenfield Filter,
56	Vena Caval Filter Use in Patients with Sepsis. 2003.	Greenfield Stainless Steel, Greenfield Percutaneous Stainless Steel, Greenfield Titanium.
57	Results of long-term venacavography study after placement of a Greenfield vena caval filter. 1992	Greenfield SGF, Greenfield, TGF, LGM (Vena-Tech)
58	LGM Vena Cava Filter: Objective Evaluation of Early Results. 1991	LGM (Vena-Tech), Greenfield
59	Percutaneous Transvenous Caval Interruption with "LGM" Filter: Early Results of a Multicenter Trial. 1988	LGM (Vena-Tech), Greenfield, Combe
60	Complications of Vena Cava Filters. 1993	Mobin-Uddin umbrella, Kimray-Greenfield stainless-steel filter, Bird's Nest, Greenfield Titanium, Simon Nitinol, Vena-Tech Filter.
61	Vena Tech-LGM Filter: Long-term Results of a Prospective Study. 1993	LGM (Vena-Tech)
62	Analysis of the Transition to Percutaneous Placement of Greenfield Filters. 1990	Greenfield
63	LGM (Vena-Tech) Vena Caval Filter:	LGM (Vena-Tech), Stainless Steel

	Experience at a Single Institution. 1994.	Greenfield, Titanium Greenfield, Bird's Nest, Nitinol
64	Simon Nitinol Inferior Vena Cava Filter: Initial Clinical Experience. 1989	SNF

Schedule 18 - SIR Guidelines and Author/Contributor Relationships with IVC Filter Companies

Schedule 18 - SIR Guidelines and Author/Contributor Relationships with IVC Filter Companies

Author	Guideline Status	Relationship(s)
Grassi, Clement	Author	Expert witness for C.R. Bard and BPV[i]
Trerotola, Scott	Acknowledged	Retained consultant/KOL for Bard, Cook, B. Braun[ii]
Venbrux, Anthony	Acknowledged	Retained consultant for Bard.[iii]

[i] Deposition of Clement J. Grassi, MD in *Austin v. C.R. Bard and BPV* (August 22, 2016). Dr. Grassi is a paid Bard consultant. (54:10-23). Dr. Grassi has worked on multiple cases and earned approximately $39,000. (54:10-23), (63:7-19).

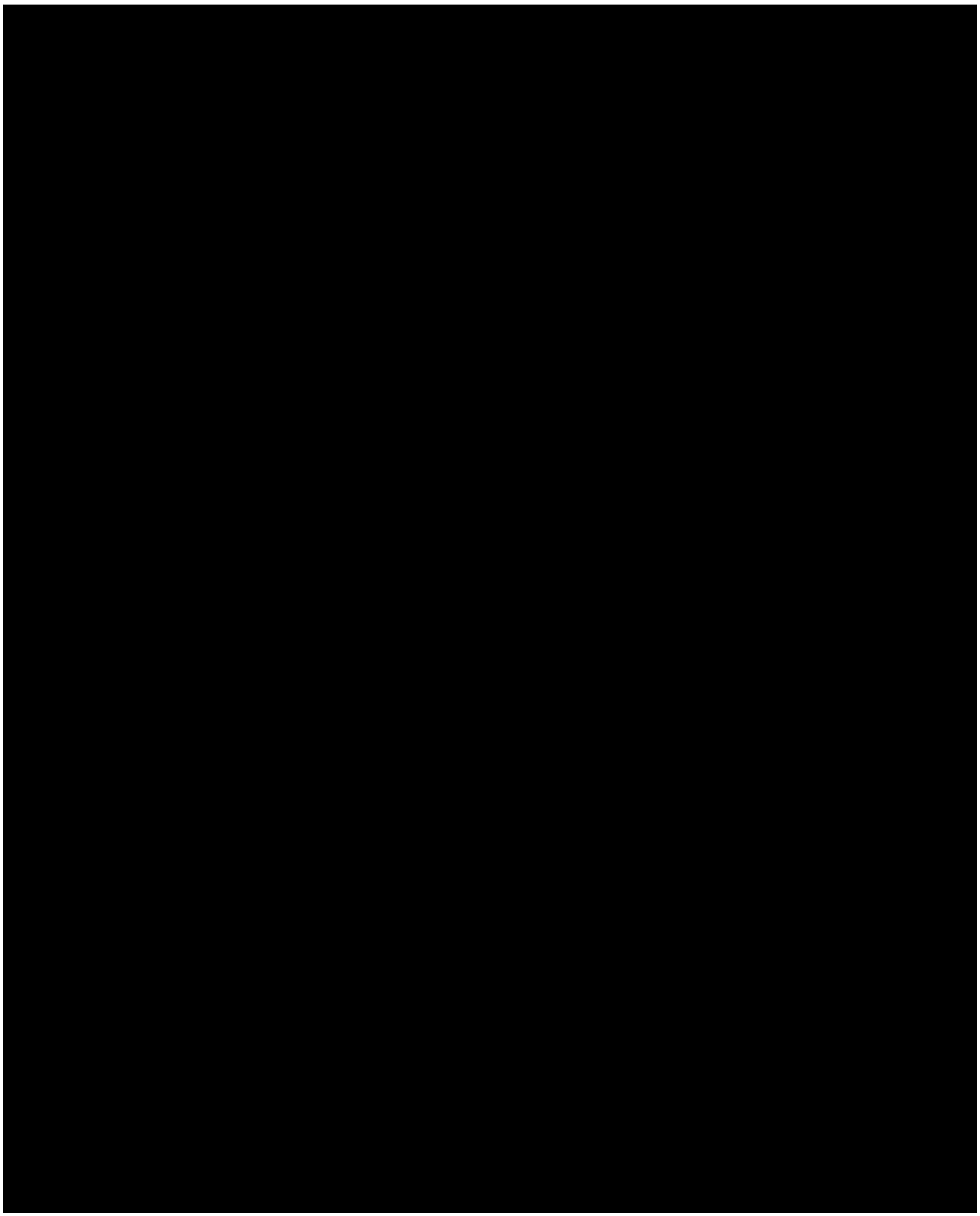
[ii] Deposition of Scott Trerotola, MD in *Katrina Newton, et al. v. C.R. Bard and BPV* (November 15, 2010). Dr. Trerotola participated in animal testing sponsored by Bard before the Recovery filter went on the market in 2003. (49:9-19). Dr. Trerotola was paid between $10,000 and 20,000 a year as a Bard consultant (144:10-16).

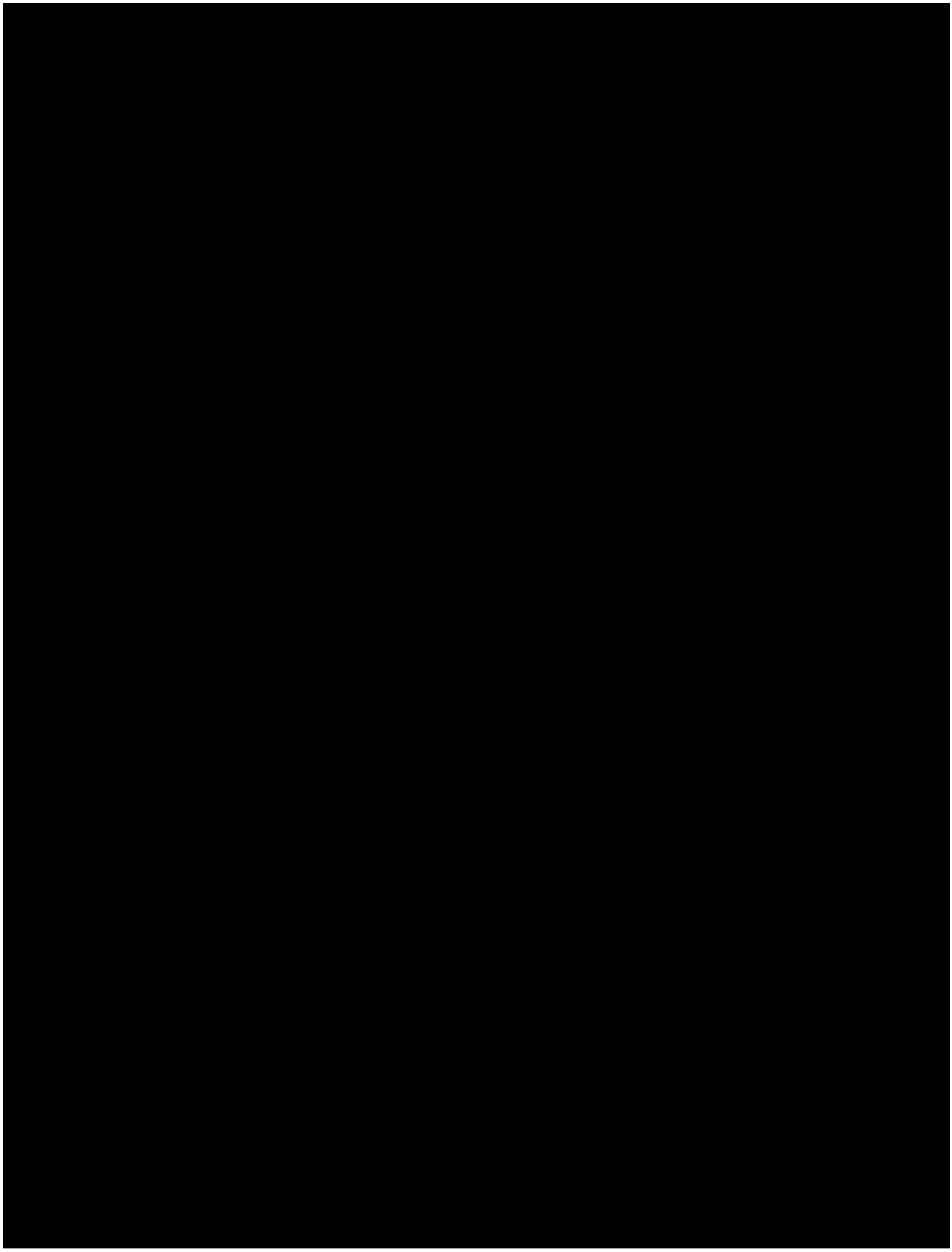
[iii] Deposition of Anthony Venbrux in *Newton v. C.R.Bard and BPV* (January 28, 2011). Venbrux has been a paid consultant for Bard since 2003. He has been paid over $188,000. (25:1- 35).

Schedule 19 - Deaths

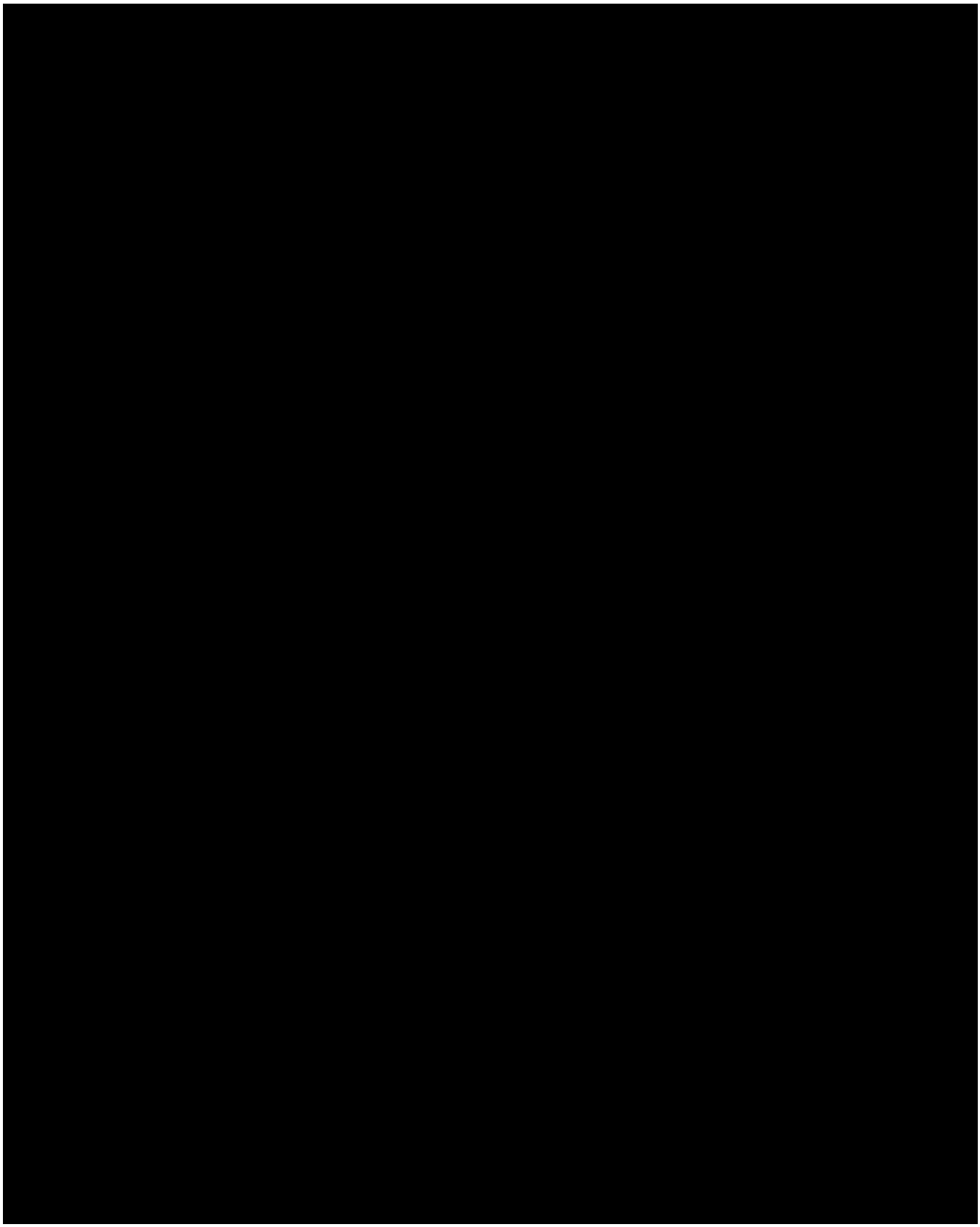
Schedule 19: Filter Related Deaths

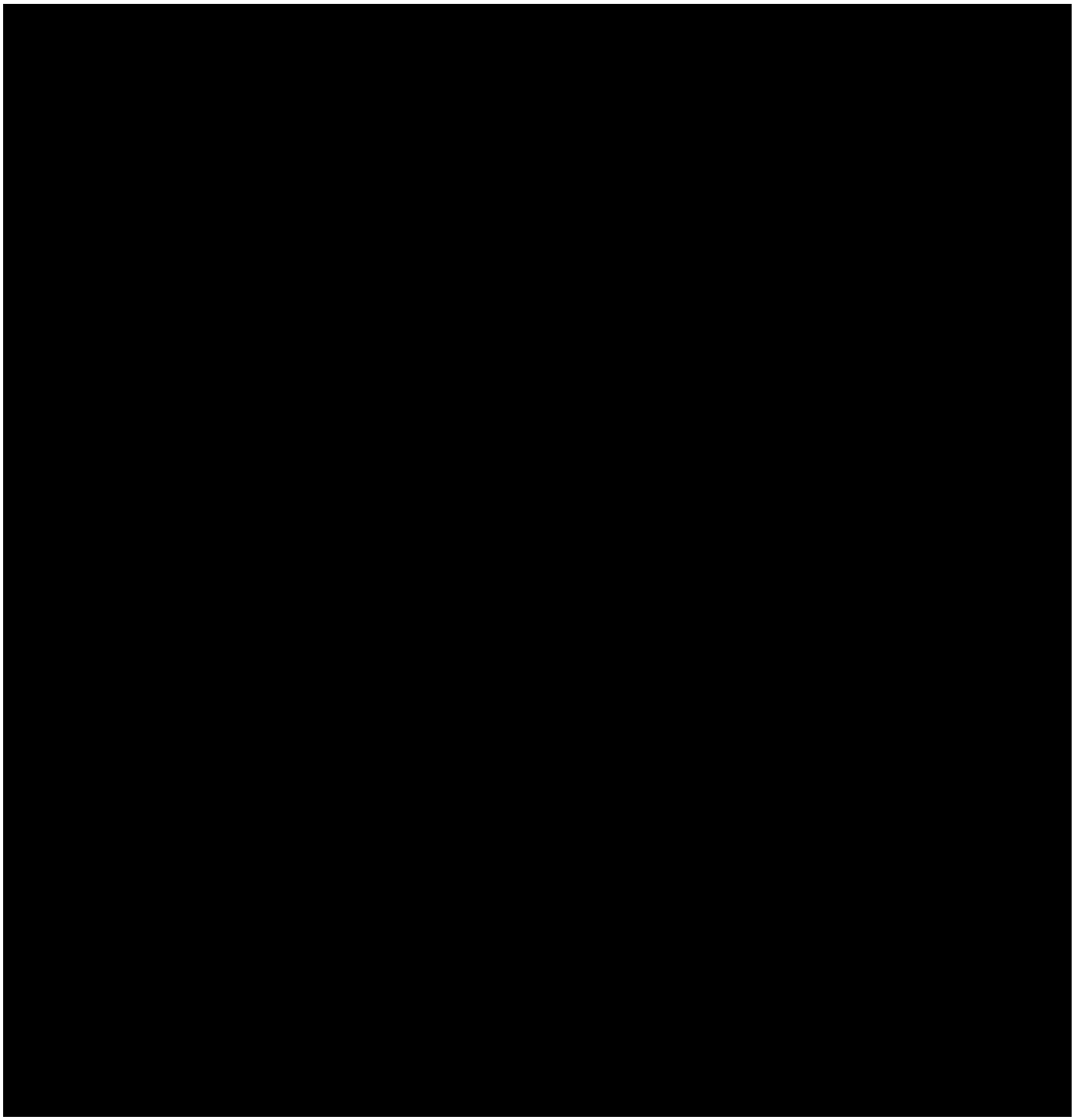
RECOVERY FILTER





G2 FILTER





ECLIPSE FILTER

MERIDIAN FILTER

Exhibit D (Cont.)

DOCUMENT SUBMITTED UNDER SEAL

Schedule 20 – Fatigue Resistance Testing

Schedule 20- Fatigue Resistance Testing - All Tests

Samples	Test type	Date	Bates	Performed by	Additional Documents
0.012" NiTi wire	Rotating-Beam Corrosion Fatigue Testing	12/30/1997	BPV-TRIAL-EXHIBIT-0183	NMT	
RNF	EnduraTEC Corrosion/Fatigue Testing	8/4/1999	BPV-TRIAL-EXHIBIT-0228	NMT	
RNF	FEA	6/9/2000	BPV-TRIAL-EXHIBIT-0319	NMT	
RNF	FEA	1/7/2005	BPVE-01-00002658	Computer Aided Engineering	
RNF+modified RNF	Arm Fatigue Test	1/10/2005	BPV-17-01-00000781	Bard	Test method at BPVE-01-00017879
RNF+G1A	FEA	2/16/2005	BPV-17-01-00096636	Bard+Computer Aided Engineering Associates	
SNF+RNF+G2	FEA	10/16/2006	BPVE-01-00818419	WJH Engineering	Addedum at BPV-17-01-00118350
RNF+G2+G2X	G2 Express Filter Arm Fatigue Comparison	11/5/2007	BPV-17-01-00133064	Bard	Test method at BPVE-01-00017879
G2X	Flat Plate Fatigue and Corrosion Examination	2/8/2008	BPVEFILTER-01-00187859	Bard	
Various wire lots, including some electropolished	Rotary Beam Fatigue	11/10/2008	BPV-17-01-00188401	Bard	

Schedule 20- Fatigue Resistance Testing - FEA Tests

Samples	Test type	Date	Bates	Performed by	Positions	Results
RNF	FEA	6/9/2000	BPV-TRIAL-EXHIBIT-0319	NMT	[redacted]	[redacted]
RNF	FEA	1/7/2005	BPVE-01-00002658	Computer Aided Engineering		
RNF+G1A	FEA	2/16/2005	BPV-17-01-00096636	Bard+Computer Aided Engineering Associates	[redacted]	[redacted]
SNF+RNF+G2	FEA	10/16/2006	BPVE-01-00818419; Addedum at BPV-17-01-00118350	WJH Engineering	[redacted]	[redacted]

Schedule 20- Fatigue Resistance Testing - Flat Plate Tests

Samples	Test type	Date	Bates	Performed by	# of cycles	Deflection	Tube size	# of Samples	Results	Notes
RNF	EnduraTEC Corrosion/Fatigue Testing	8/4/1999	BPV-TRIAL-EXHIBIT-0228	NMT	[redacted]					
RNF+modified RNF	Arm Fatigue Test	1/10/2005	BPV-17-01-00000781; Test method at BPVE-01-00017879	Bard						
G2X	Flat Plate Fatigue and Corrosion Examination	2/8/2008	BPVEFILTER-01-00187859	Bard						
RNF+G2+G2X	G2 Express Filter Arm Fatigue Comparison	11/5/2007	BPV-17-01-00133064; Test method at BPVE-01-00017879	Bard						

Schedule 20- Fatigue Resistance Testing - Rotary Beam Tests

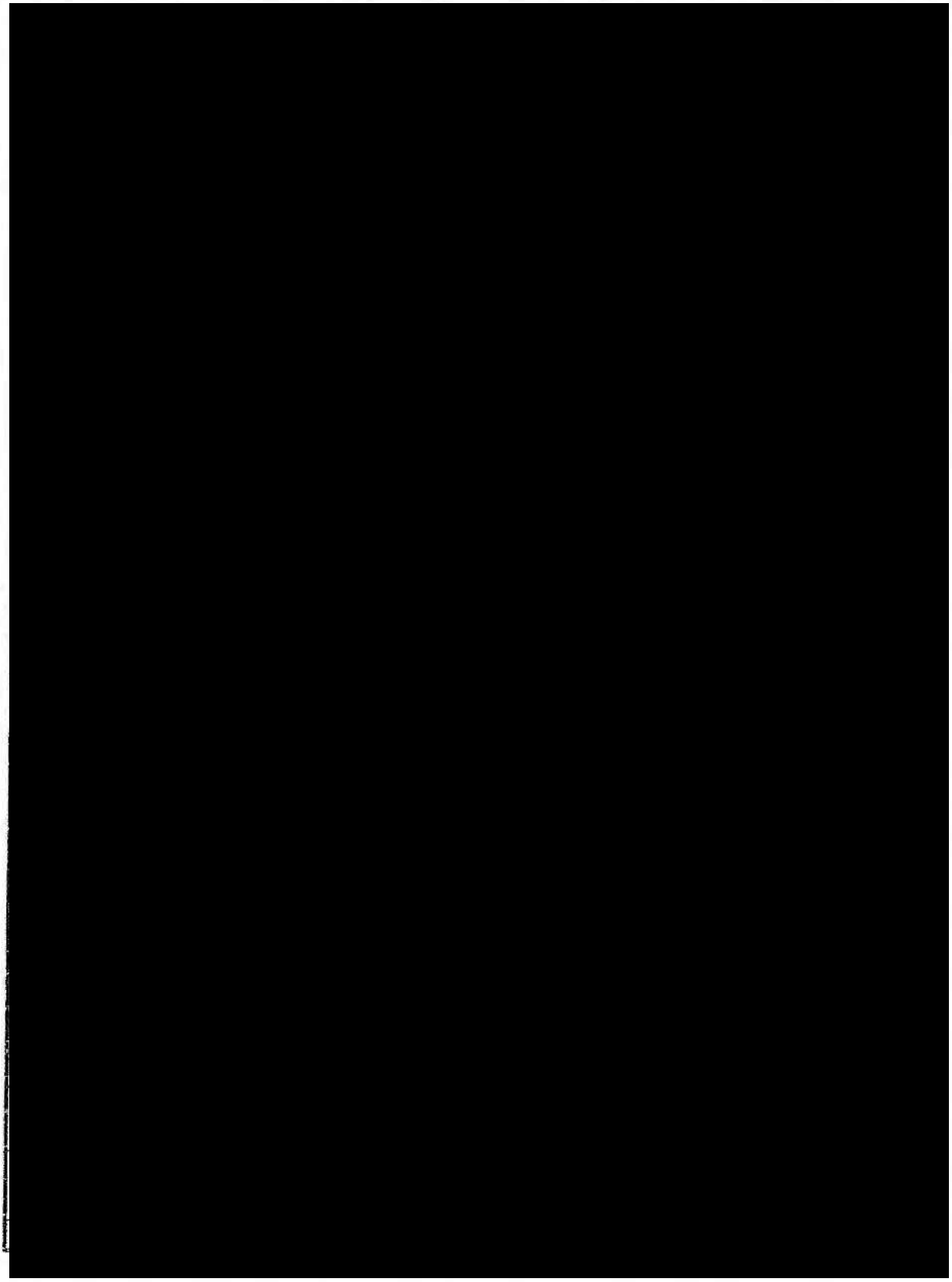
Samples	Test type	Date	Bates	Performed by	# of cycles	Load	Results
0.012" NiTi wire	Rotating-Beam Corrosion Fatigue Testing	12/30/1997	BPV-TRIAL-EXHIBIT-0183	NMT	[redacted]		
Various wire lots, including some electropolished	Rotary Beam Fatigue	11/10/2008	BPV-17-01-00188401	Bard			

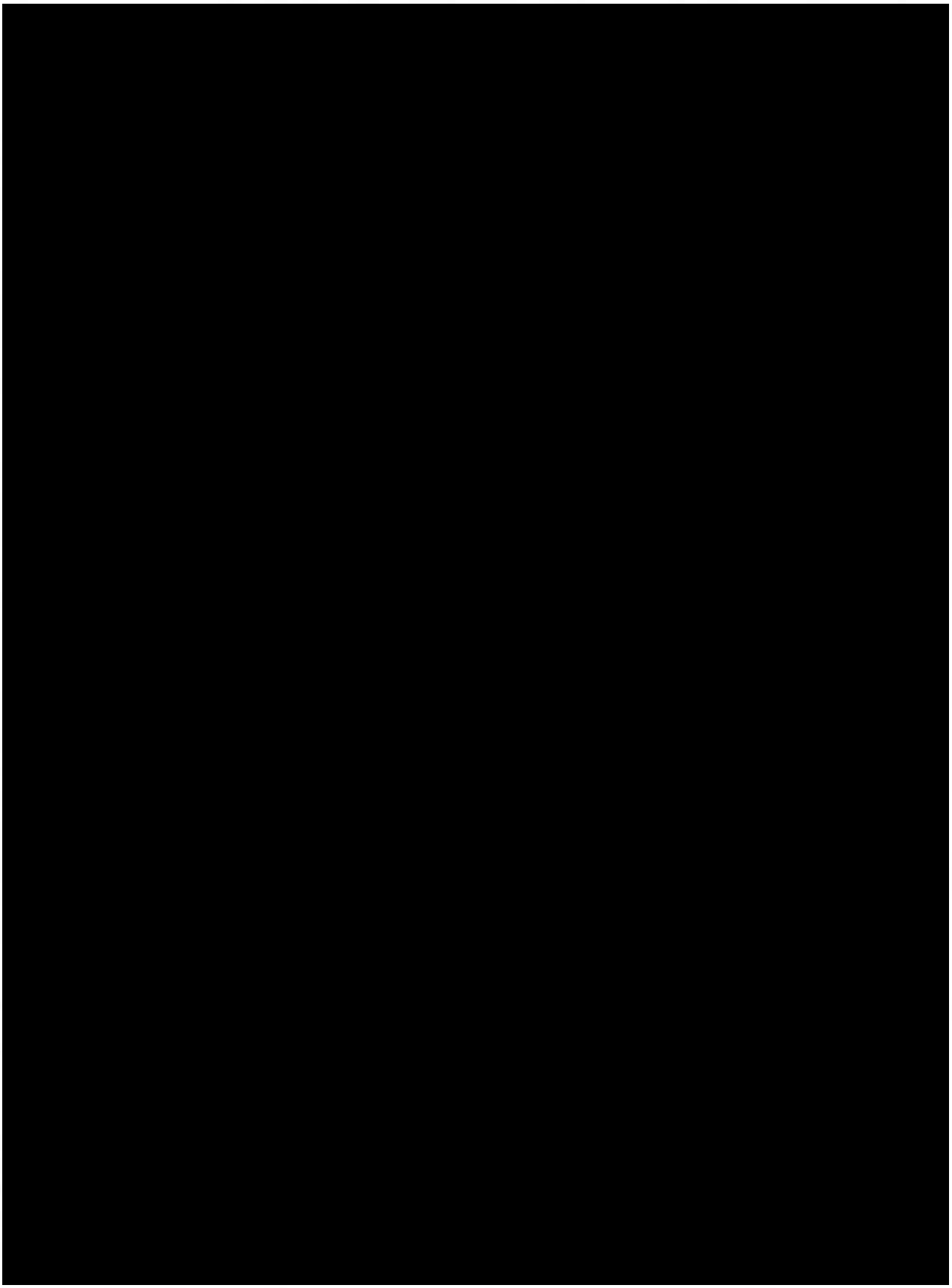
Schedule 21- FDA and Bard communications regarding Form 483 and Warning Letter

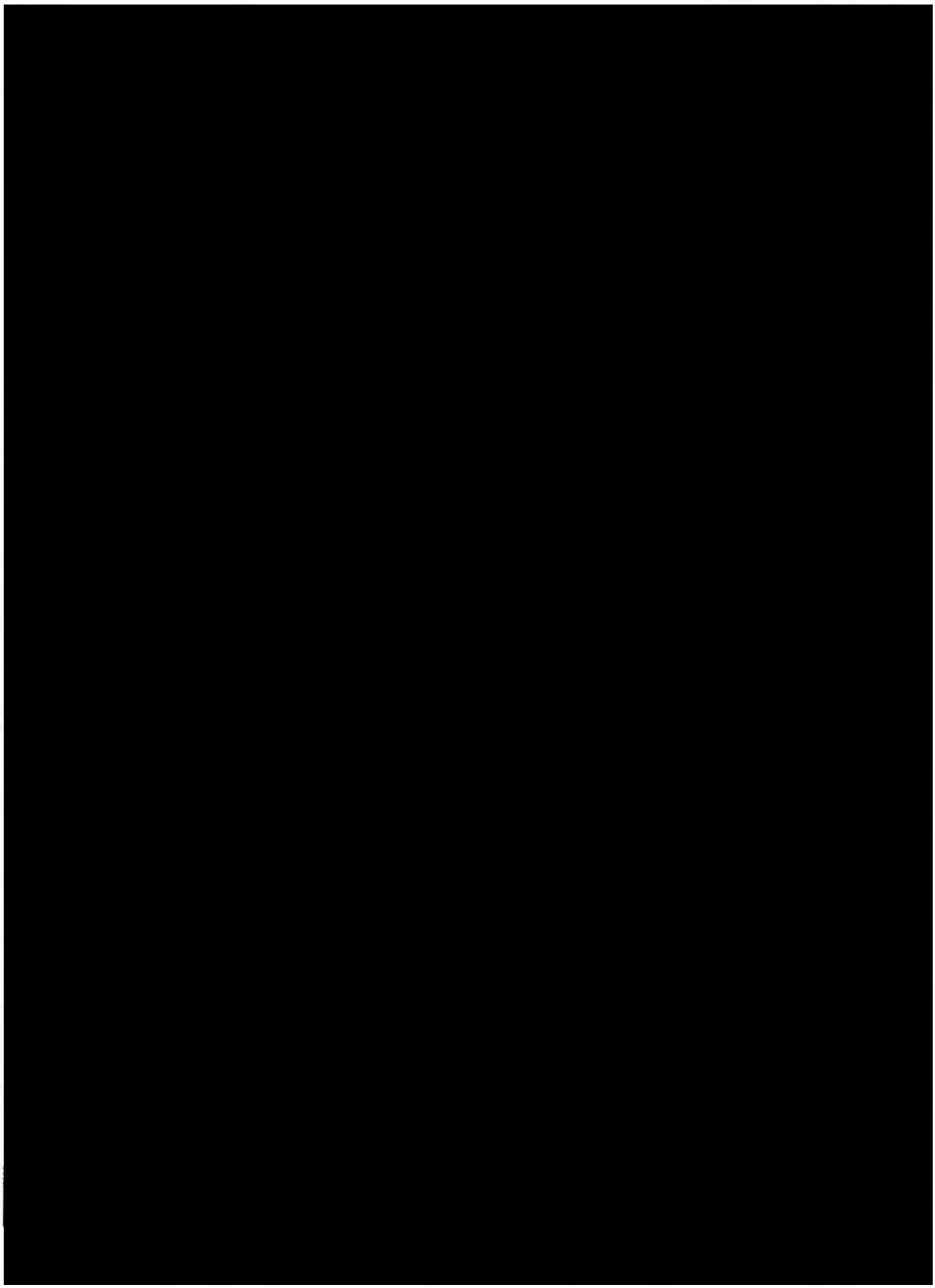
Schedule 21 - Form 483 and FDA Warning Letter

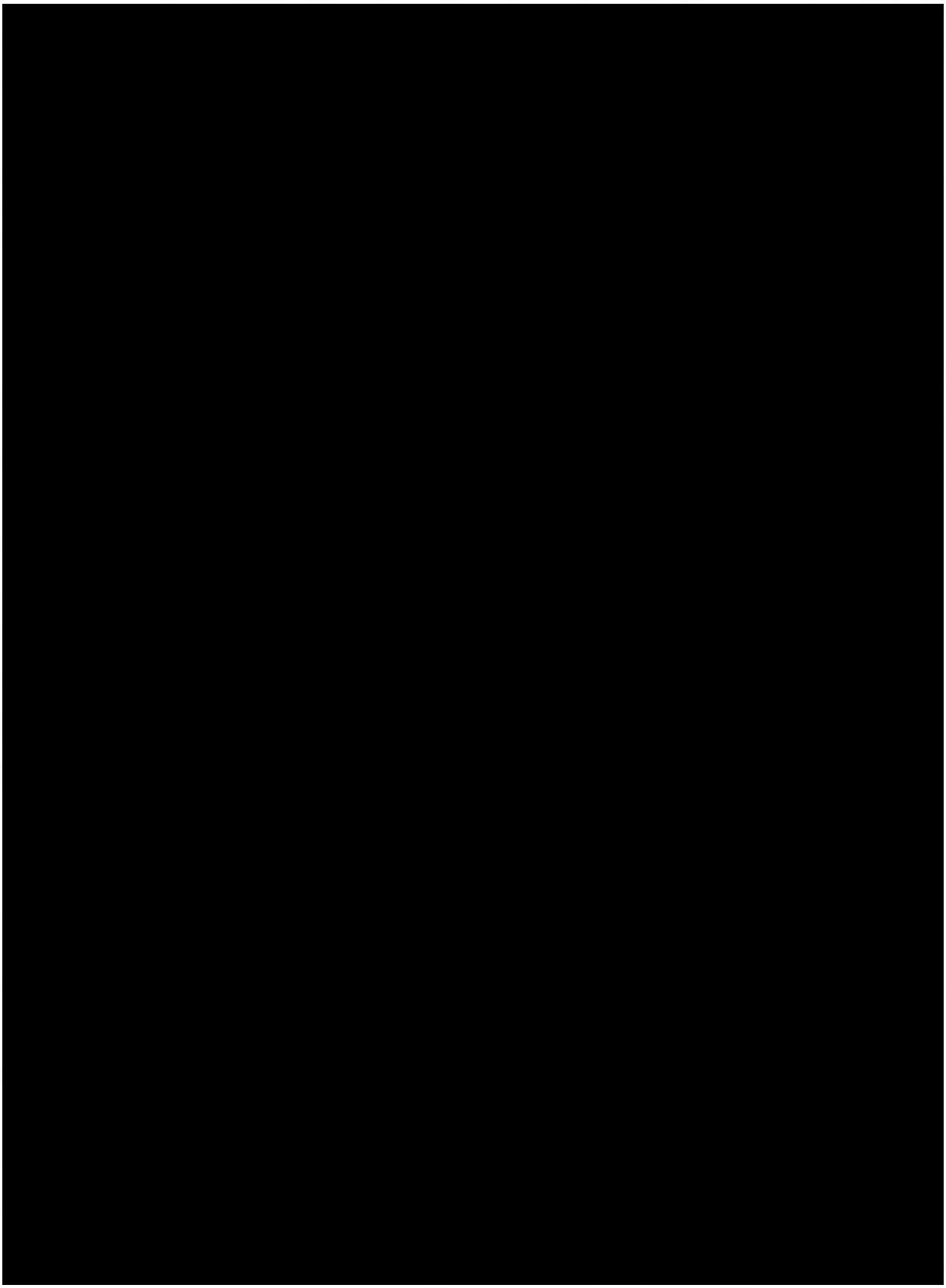
Date	Device	Summary
11/25/2014	All	Form 483 issued to Queensbury, NY to Glen Falls Operation
12/17/2014 -11/20/2015	All	Bard responds to 11/25/14 Form 483
1/5/2015	Meridian, Denali	Form 483 issued to Tempe, AZ facility
1/23/2015	Meridian, Denali	Bard creates VT-CAPA-15-002 to address Tempe AZ Form 483 observations
1/26/2015	Meridian, Denali	Bard creates VT-CAPA-15-003 to address Tempe AZ Form 483 observations
1/26/2015 - 9/3/2015	Meridian, Denali	Bard's initial response and six update to 1/5/15 Tempe AZ Form 483
7/13/2015	All	FDA issues a Warning Letter to Bard
7/17/2015	Recovery Cone FBRC	Bard ceases shipment of the Recovery Cone Model FBRC
7/30/2015	Recovery Cone FBRC	510(k) Submission for Recovery Cone Models RC-15 and FBRC
7/30/2015	Recovery Cone	Bard submits a new 510(k) notice to cover both models of the Recovery Cone (RC-15 and FBRC) K152136.
8/3/2015 - 11/20/2015	Recovery Cone, All	Bard's responds to FDA Warning Letter.
10/26/2015	All	Meetings with the FDA re MDR Reportability
11/4/2015	All	Meetings with the FDA re MDR Reportability
12/8/2015	All	FDA issues follow-on Warning Letter
12/22/2015		Bard responds to Form 483, Warning Letter and 12/8/15 follow-on Warning Letter
2/16/2016	Recovery Cone FBRC	FDA approves Bard's 510(k) submission for the Recovery Cone
2/26/2016	All	Form 483 Issued to Bard, Tempe AZ Facility
3/2/2016	All	Form 483 Issued to Bard, GFO, NY Facility
3/11/2016	All	Bard's initial response to 2/26/16 Form 483
3/22/2016	All	Emails between FDA and Bard about complaints/MDRs cited in the warning letter
3/22/2016	All	Bard's update to 3/2/16 Form 483
4/11/2016	All	Bard's second update to 2/26/16 Form 483

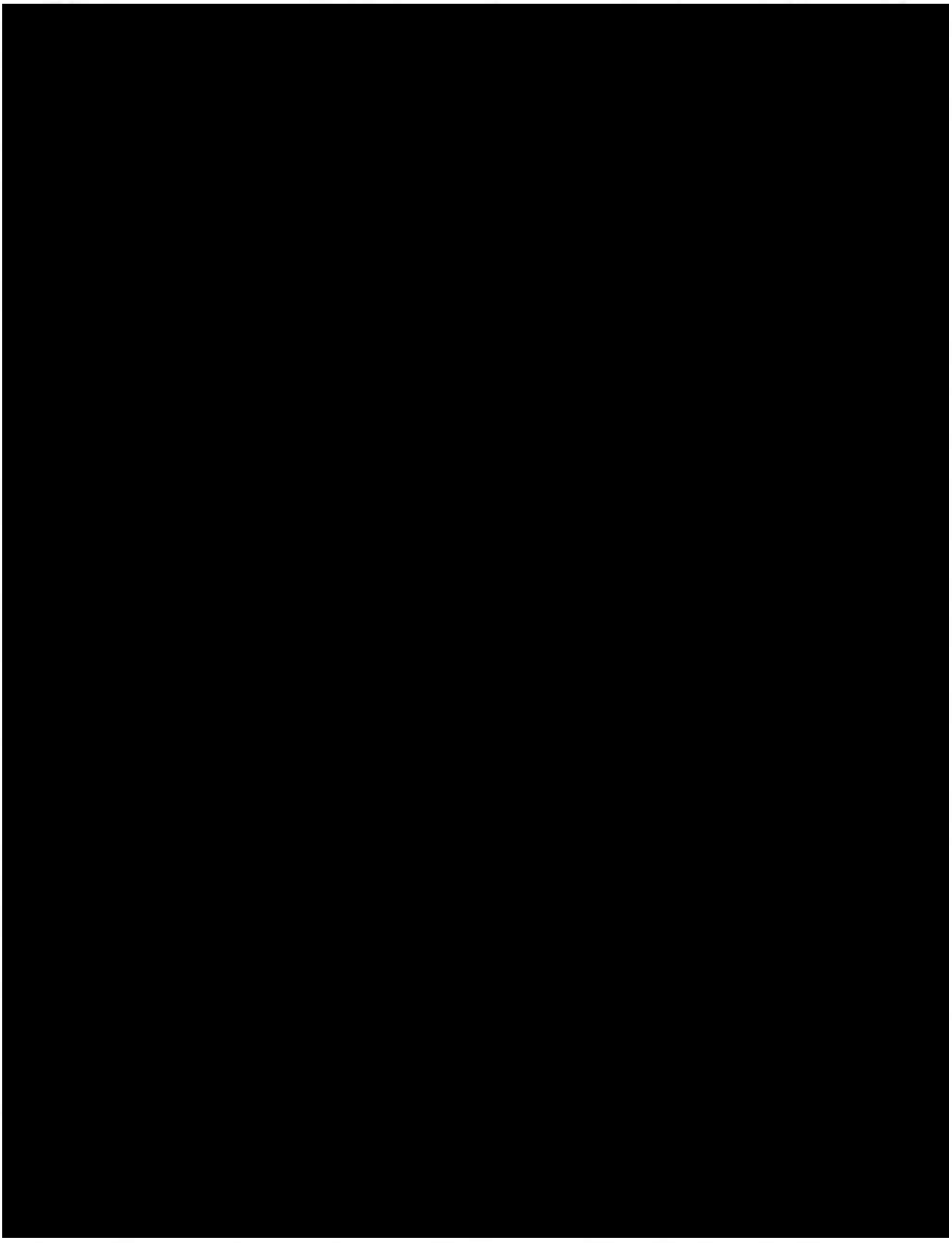
[redacted]

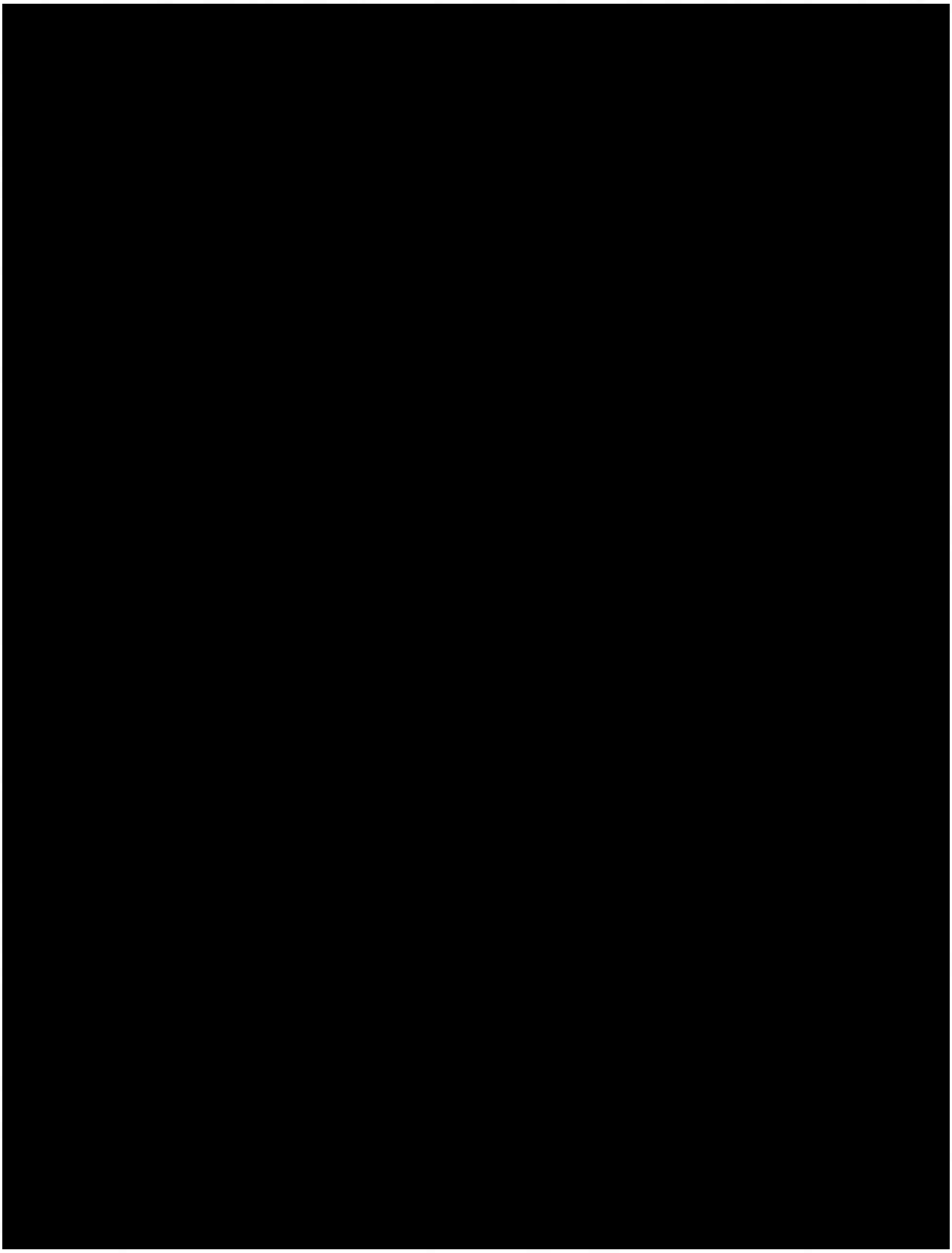


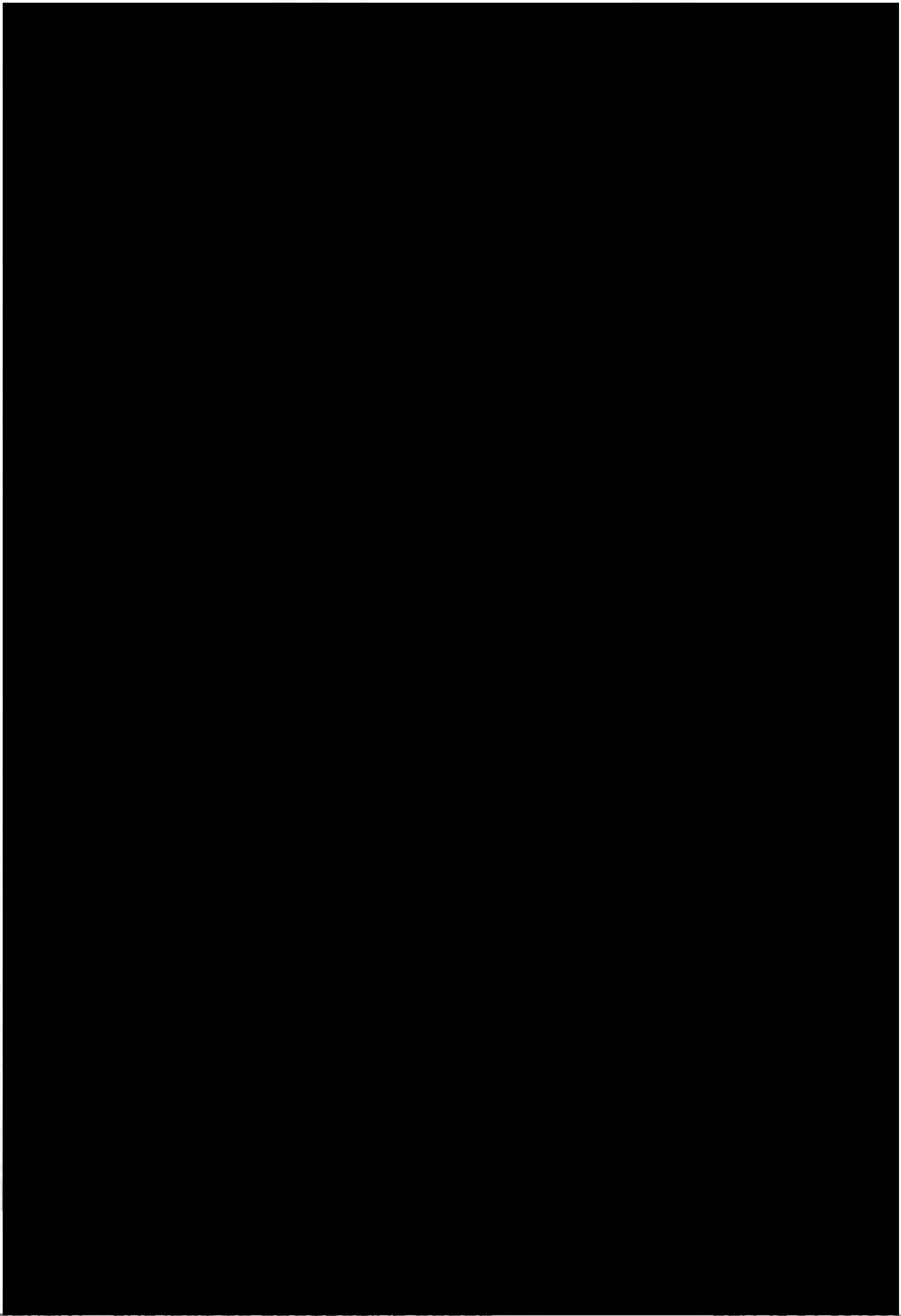


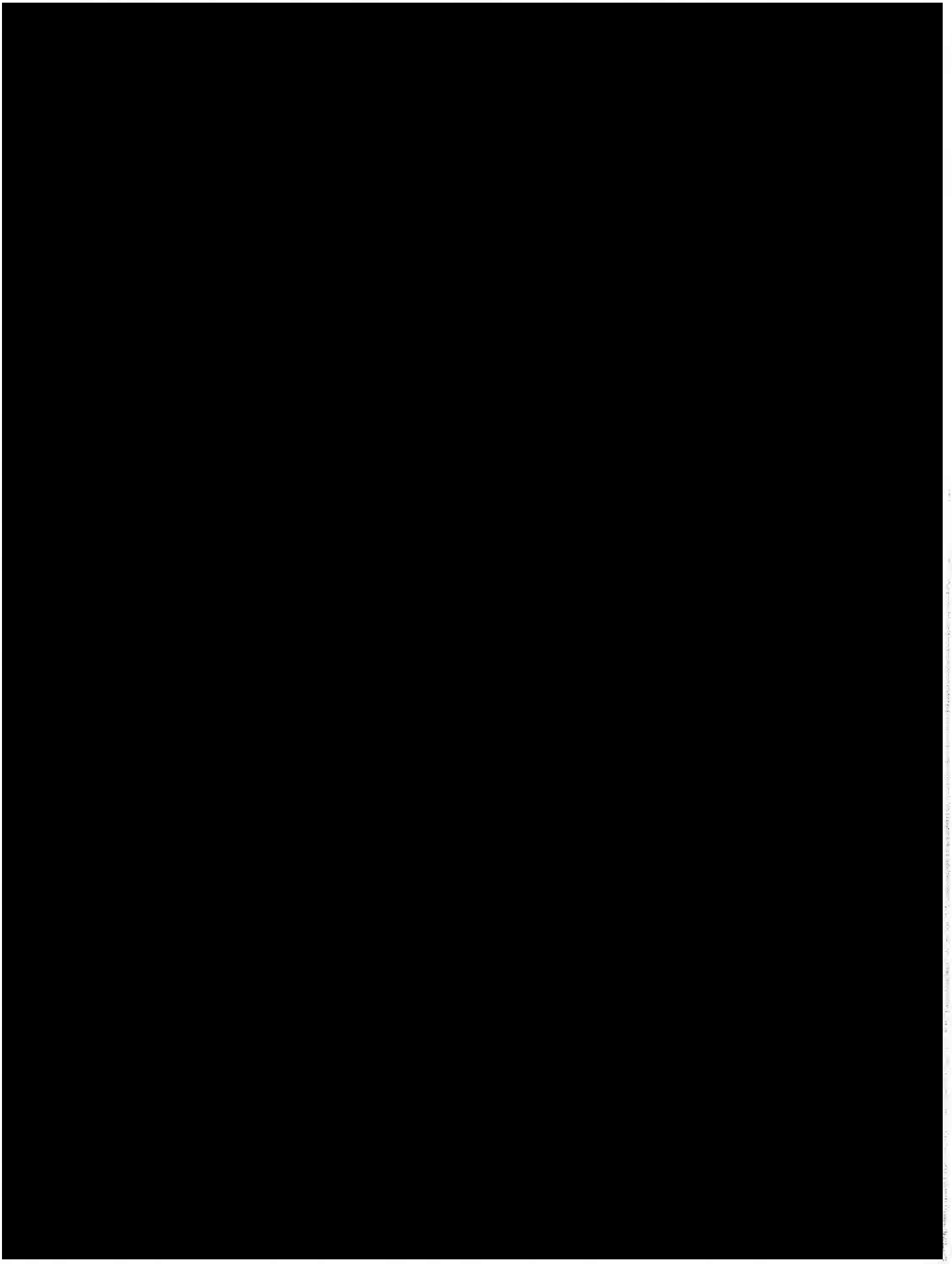


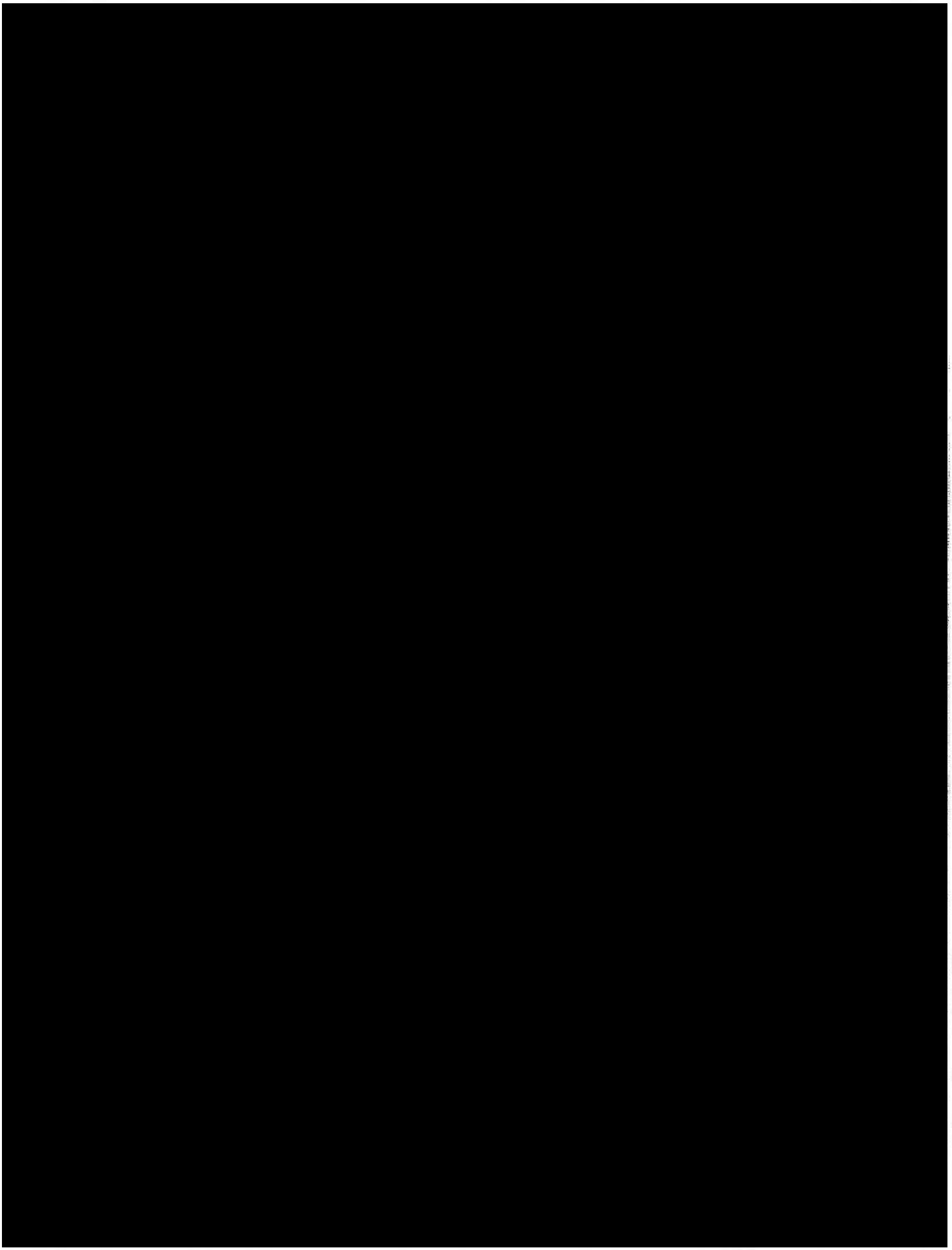


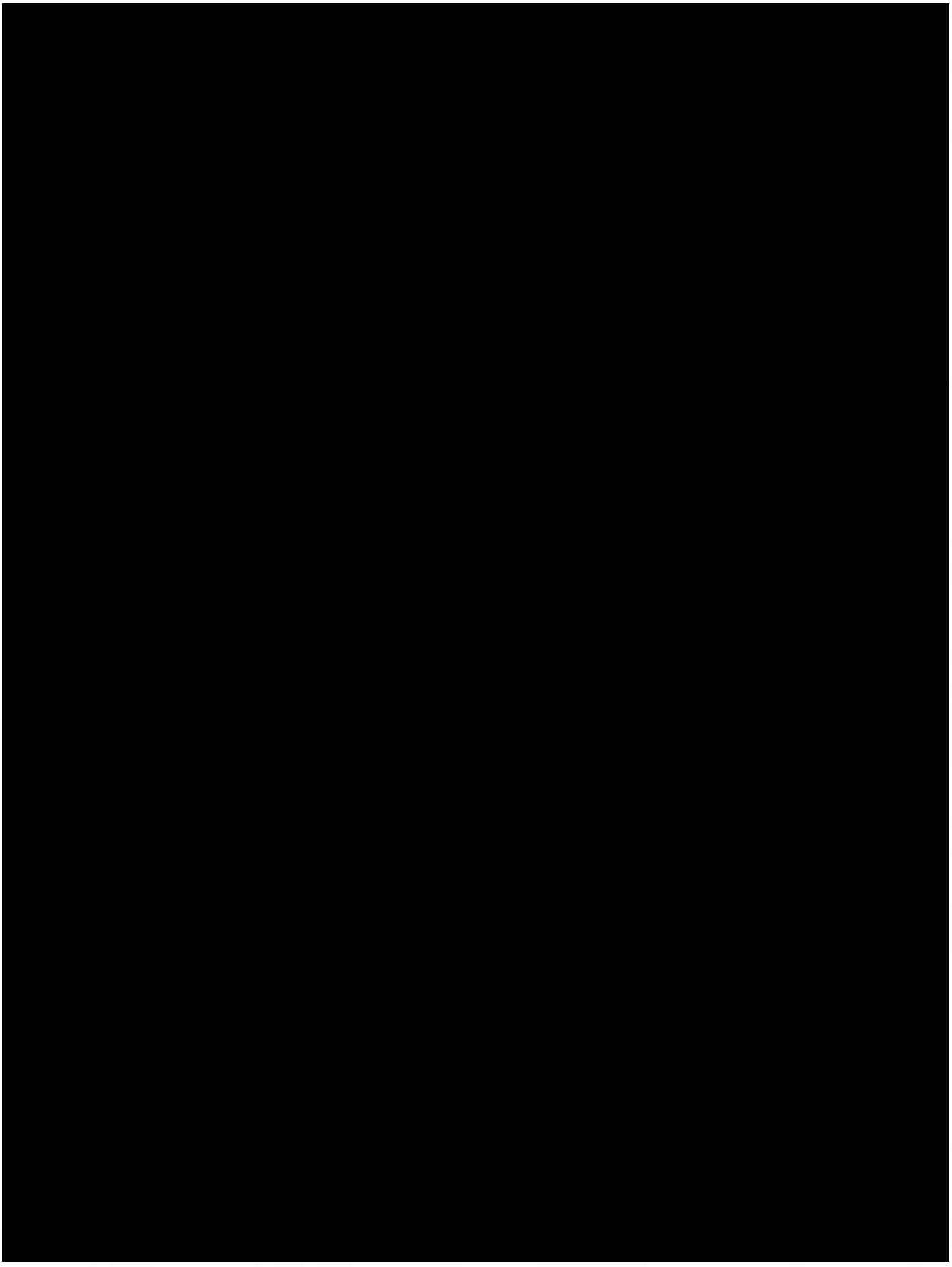


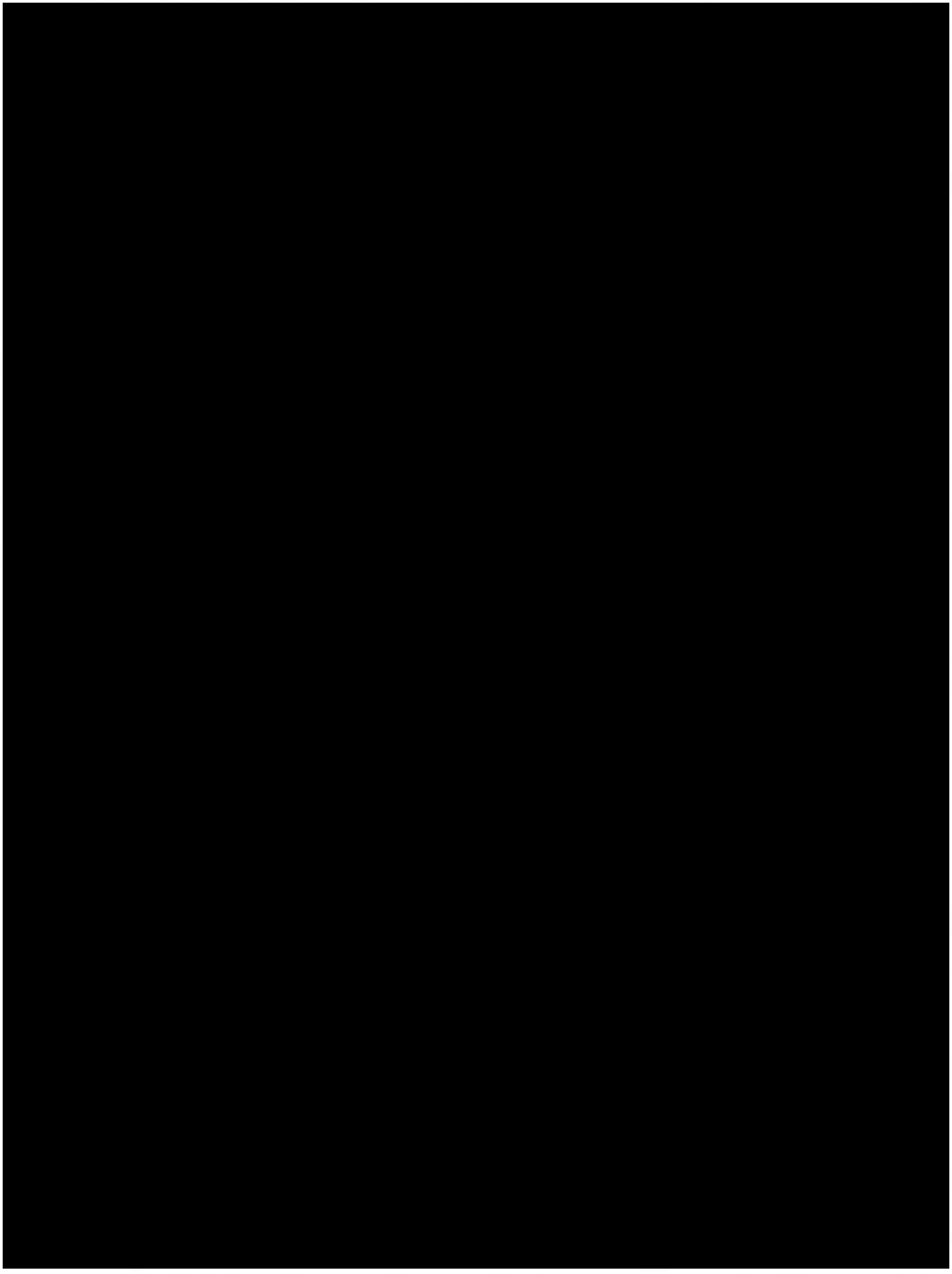


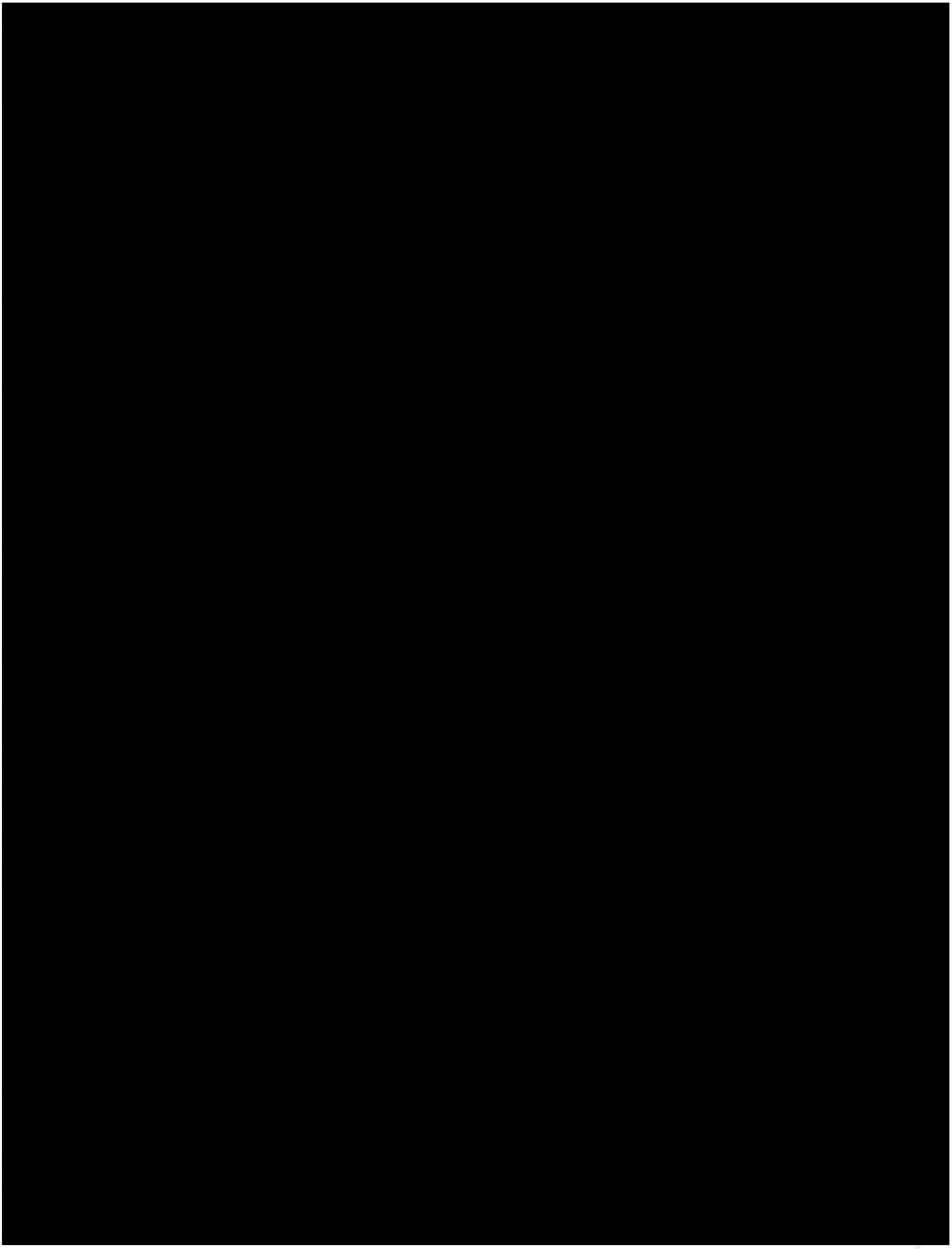


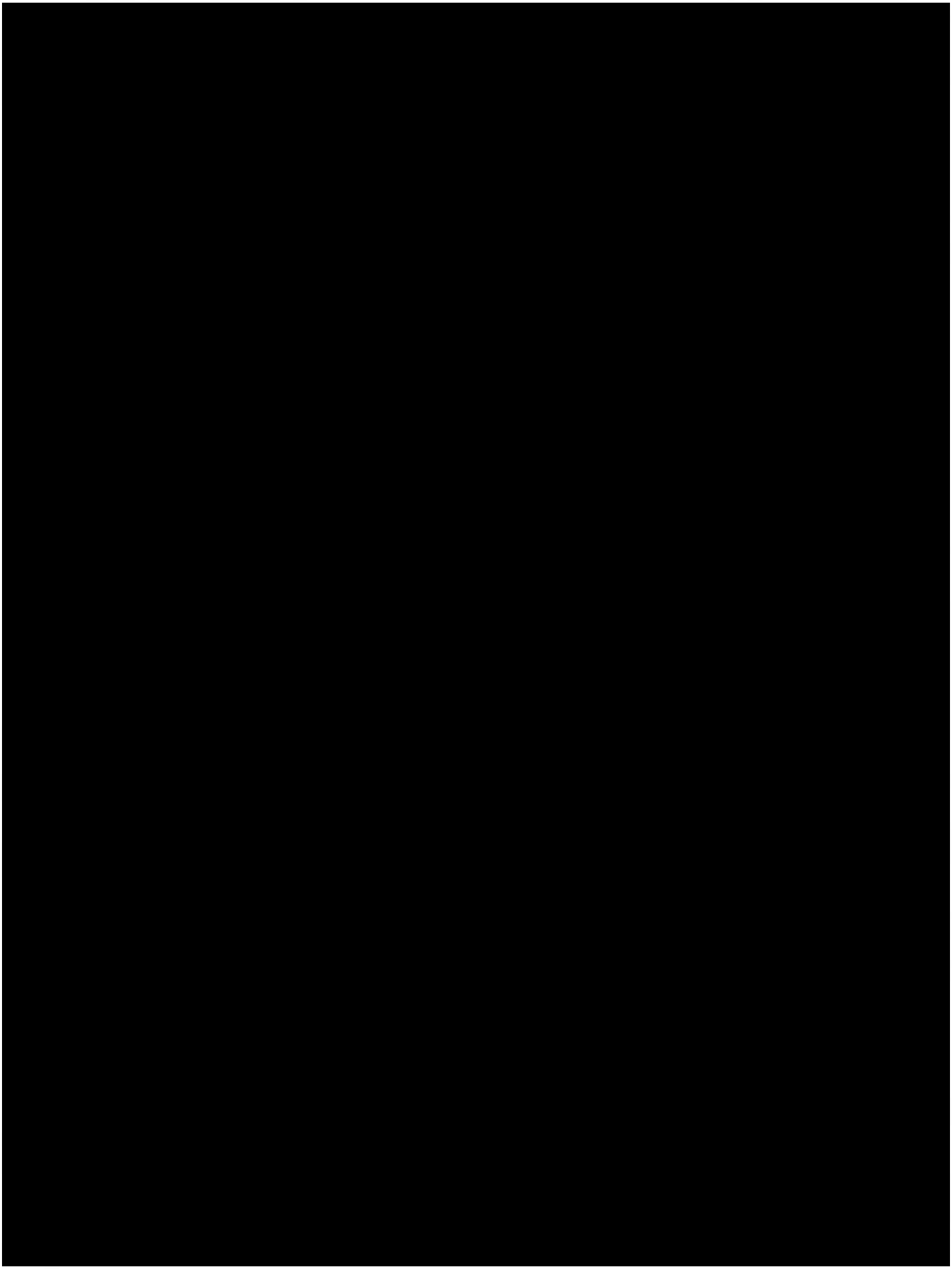


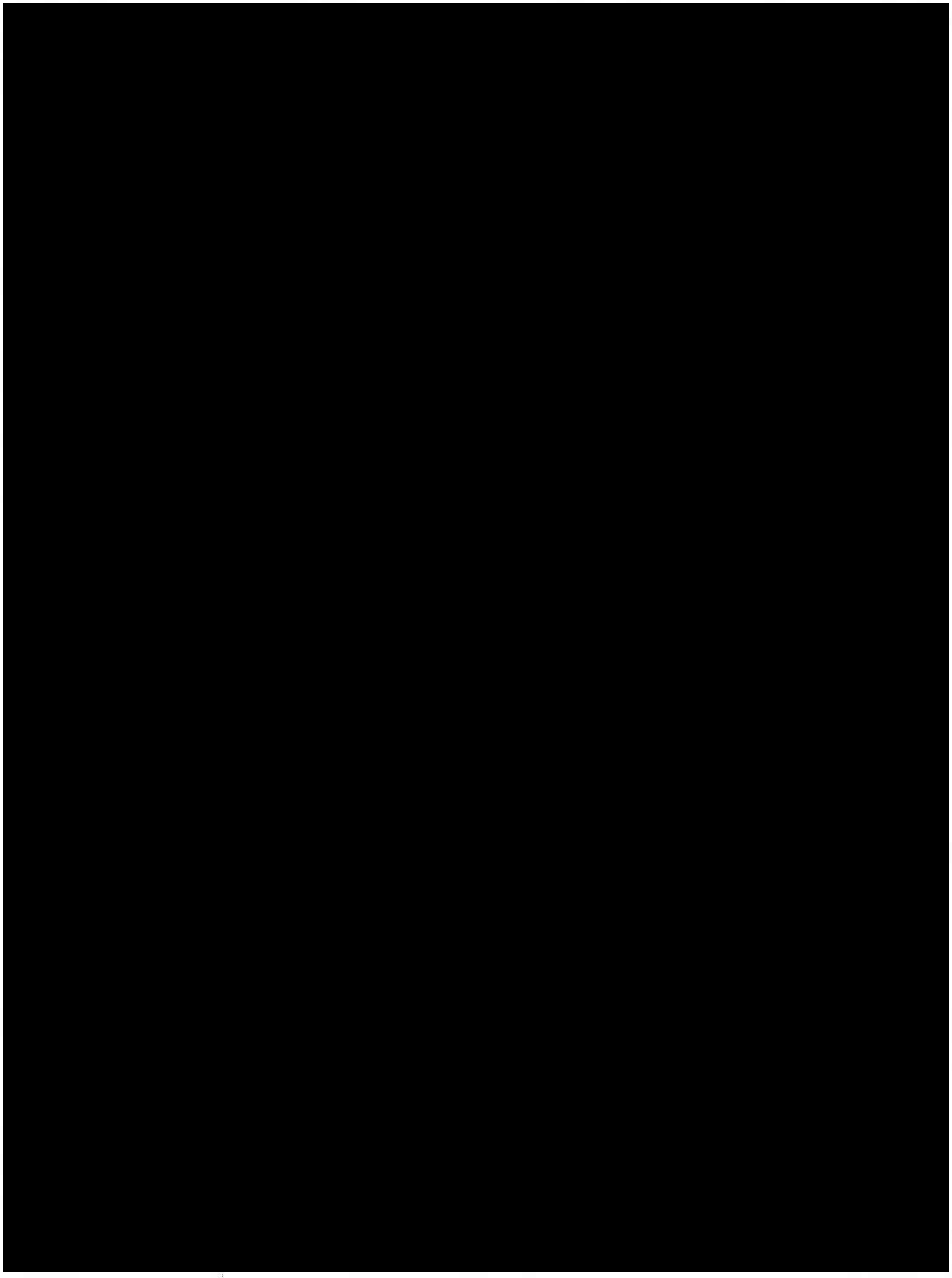


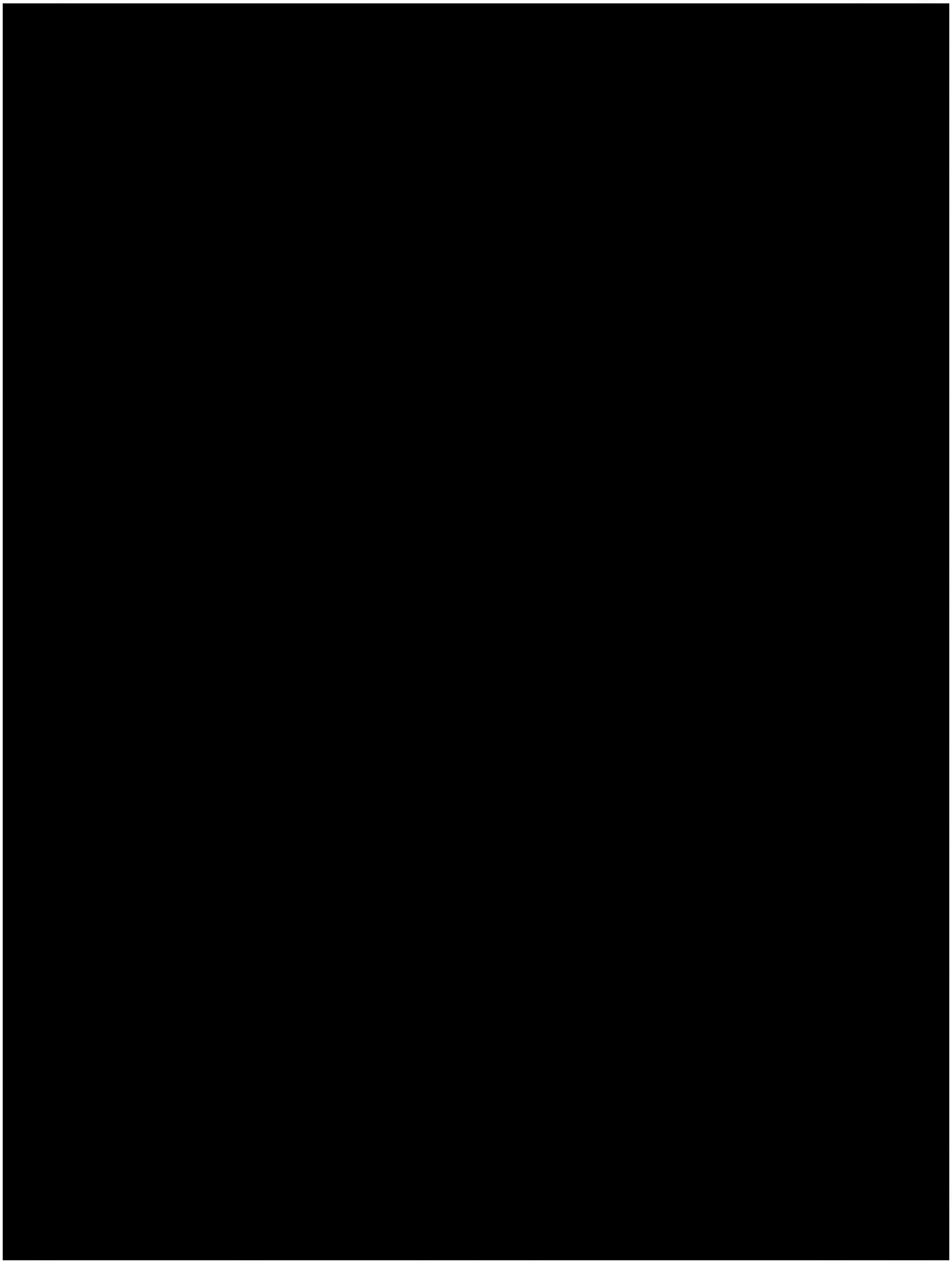


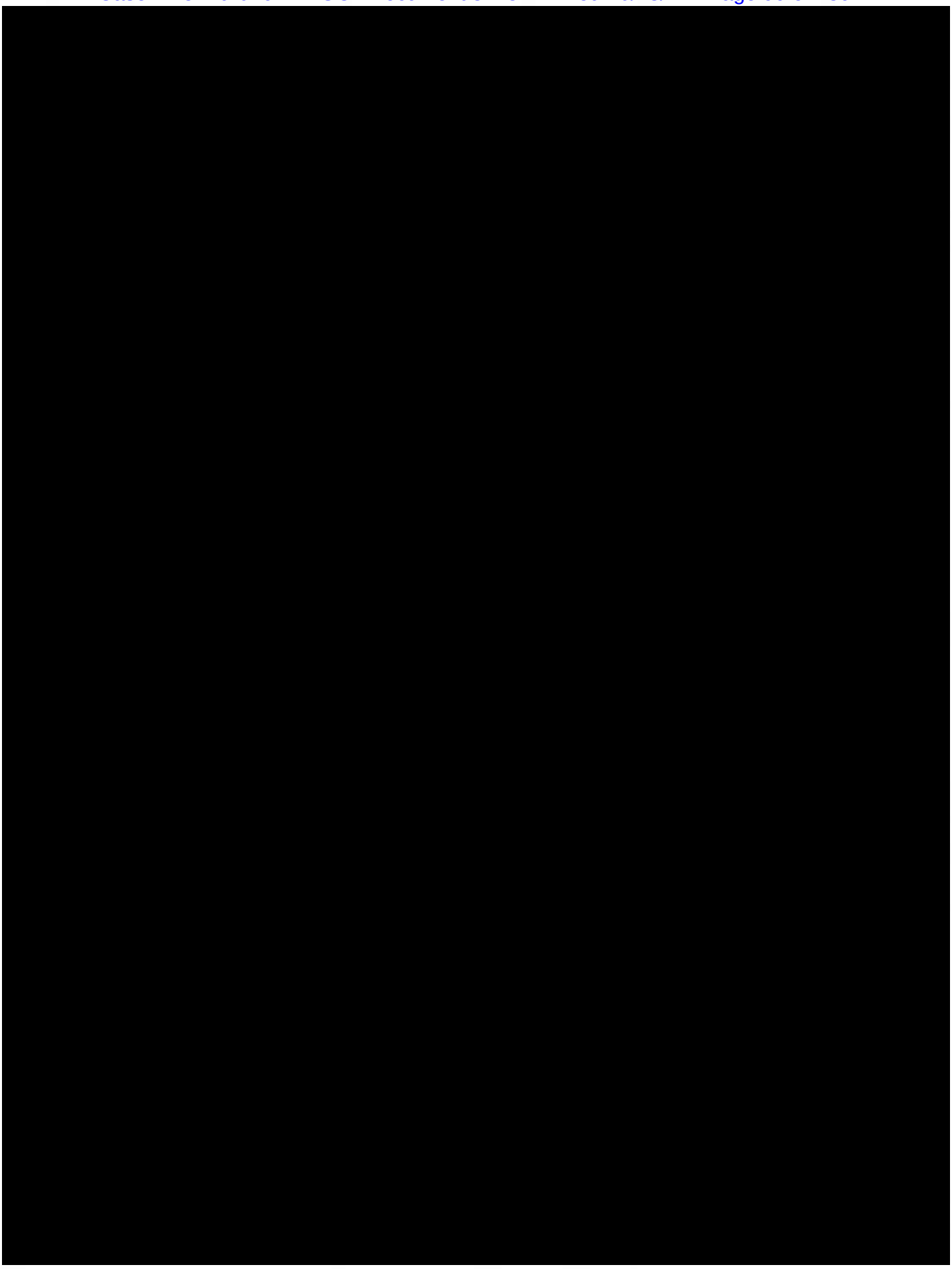












U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

C.R. Bard, Inc. 7/13/15

Department of Health and Human Services

Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612
Telephone: 949-608-2900
Fax: 949-608-4415

WARNING LETTER

VIA UNITED PARCEL SERVICE
SIGNATURE REQUIRED

July 13, 2015

W/L # 27-15

Timothy M. Ring
Chairman and Chief Executive Officer
C.R. Bard Inc.
730 Central Ave.
Murray Hill, NJ 07974

Dear Mr. Ring:

During inspection of your C.R. Bard Inc. facility located at 289 Bay Rd, Queensbury, NY, on October 6, 2014, through November 25, 2014, and during inspection of your Bard Peripheral Vascular facility located at 1625 W. 3rd St., Tempe, AZ, on November 18, 2014, through January 05, 2015, investigators from the United States Food and Drug Administration (FDA) determined that your firm is a specification developer and manufacturer for the Inferior Vena Cava (IVC) filter delivery systems and components, including, but not limited to, the Denali Filter, the Simon Nitinol Filter and Recovery Cone Removal Kit. This warning letter addresses violations found at the Bard Peripheral Vascular facility located at 1625 W. 3rd St., Tempe, AZ and C.R. Bard Inc. facility

located at 289 Bay Rd, Queensbury, NY. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or any function of the body.

We received responses dated December 17, 2014, January 15, 2015, February 18, 2015, March 16, 2015, April 17, 2015, and May 6, 2015, from Mr. Jason J. Gaede, Vice President Plant Operations, C.R. Bard Inc., Queensbury, NY. We also received responses dated January 26, 2015, February 26, 2015, March 26, 2015, April 24, 2015, and May 22, 2015, from Steve S. Williamson, President, Bard Peripheral Vascular, a Division of C.R. Bard, Tempe, AZ. These were responses to the observations noted on Form FDA 483s, Lists of Inspectional Observations that were issued to you at the close of our inspections. We address your responses below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

Adulteration/Misbranding Violations at the Tempe, AZ facility

1. FDA has learned that your firm manufactures the Recovery Cone Removal System, Model RC-15 in the United States without marketing clearance or approval, in violation of the Act. Under section 201(h) of the Act, 21 U.S.C. § 321(h), this product is a device because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or any function of the body. As explained below, this device is being marketed without the required clearance or approval.

The Recovery Cone Removal System, Model RC-15 is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because you do not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g). The Recovery Cone Removal System, Model RC-15 is also misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because you did not notify the agency of your intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k).

FDA reviewed labeling for the Recovery Cone Removal System, Model RC-15, which revealed that this device is intended to percutaneously remove the Recovery Filter, Recovery G2 Filter and the G2X Filter as indicated. FDA is aware that your firm submitted both in-vitro and in-vivo testing demonstrating the use of the Recovery Cone Removal System, Model RC-15 for removal of the Recovery Filter (K031328), the G2X Filter (K082305), the G2 Express Filter (K080668), and the G2 Filter (K073090). However, the Recovery Cone System, Model RC-15 was not included as part of the clearances for any of the aforementioned IVC filters. Therefore, your firm is marketing the Recovery Cone Removal System, Model RC-15 in the United States without marketing clearance or approval. Percutaneous retrieval systems, such as the Recovery Cone Removal System, Model RC-15, are regulated as manual surgical instruments intended for specialized use within a specific medical specialty, and thus require marketing authorization in order to be legally marketed in the United States.

Your firm has not submitted any correspondence to FDA regarding this violation to date.

2. FDA has also learned that your firm manufactures the Recovery Cone Removal System, Model FBRC in the United States without marketing clearance or approval, in violation of the Act. Under section 201(h) of the Act, 21 U.S.C. § 321(h), this product is a device because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or intended to affect the structure or any function of the body. As explained below, this device is being marketed without the required clearance or approval.

The Recovery Cone Removal System, Model FBRC is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because you do not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e (a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g) for the device as described and marketed. The Recovery Cone Removal System, Model FBRC is also misbranded under section 502(o) the Act, 21 U.S.C. 352(o), because you introduced or delivered into interstate commerce for commercial distribution a device with major changes/modifications to the intended use without submitting a new premarket notification to the agency as required by section 510(k), 21 U.S.C. 360(k), and 21 C.F.R. 807.81(a)(3)(ii).

You have listed the Recovery Cone Removal System, Model FBRC as a class I surgical snare under 21 CFR 878.4800. Devices classified under 21 CFR 878.4800 (Surgical Instrument, Manual) are exempt from premarket notification, unless they exceed the limitations on exemptions at 21 CFR 878.9(a). However, there is evidence that the Recovery Cone Removal System, Model FBRC is intended for uses that are different from those of legally marketed devices under 21 CFR 878.4800 (Surgical Instrument, Manual). Devices of this type usually consist of a non-powered, hand-held, or hand-manipulated device that is either reusable or disposable, which are intended to be used in general surgical procedures. Manual surgical instruments intended for specialized uses within a specific medical specialty are classified under regulations separate from 21 CFR 878.4800, depending on the labeled specialized use of the device. However, your firm is marketing the Recovery Cone Removal System, Model FBRC for a specialized intended use, namely percutaneous removal of inferior vena cava filters, specifically your firm's G2X Filter, G2 Express Filter, and G2 Filter. The labeling for the Recovery Cone Removal System, Model FBRC also indicates that your product is intended to percutaneously remove a foreign body.

Based on the above, FDA believes that the Recovery Cone Removal System, Model FBRC is regulated as a percutaneous retrieval system, which is a manual surgical instrument intended for specialized use within a specific medical specialty, cardiovascular surgery. Because there is evidence that the Recovery Cone Removal System, Model FBRC is intended for uses that are different from those of legally marketed devices classified under 21 CFR 878.4800, it exceeds the limitations described in 21 C.F.R. 878.9(a) and is not exempt from premarket notification.

Your firm has not submitted any correspondence to the FDA regarding this violation to date. For a device requiring premarket approval, the notification required by section 510(k) of the Act, 21 U.S.C. § 360(k), is deemed satisfied when a PMA is pending before the agency. 21 C.F.R. 807.81 (b). The kind of information you need to submit in order to obtain approval or clearance for your device is described on the Internet at **http://www.fda.gov/cdrh/devadvice/3122.html (http://www.fda.gov/cdrh/devadvice/3122.html)**. The FDA will evaluate the information you submit and decide whether your product may be legally marketed.

FDA requests that Bard Peripheral Vascular immediately cease activities that result in the misbranding or adulteration of the Recovery Cone Removal System, Model RC-15 and the Recovery Cone Removal System, Model FBRC, such as the commercial distribution of the devices for the uses discussed above.

Quality System Violations

The inspections also revealed that these devices are adulterated within the meaning of section 501 (h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820.
The inspection of your Bard Peripheral Vascular Facility located at 1625 W. 3rd St., Tempe, AZ also revealed that the IVC Denali Filter Delivery System is misbranded under Section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information regarding the devices that is required by or under Section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 803 - Medical Device Reporting.

Quality System Regulation Violations at the Tempe, AZ facility and Queensbury, NY facility

3. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints as required by 21 CFR 820.198(a). Your current procedures governing complaint investigation activities at your facilities, **(b)(4)** Standard for Product Complaint Handling **(b)(4)** and **(b)(4)**, Standard for Complaint Investigation Process **(b)(4)**, Complaint Investigation Activity **(b)(4)**, BPV Complaint Handling System, **(b)(4)**, Complaint Investigation Procedures, **(b)(4)** do not ensure product complaints are adequately evaluated. For example:

a. Your current procedures governing complaint investigation activities, **(b)(4)** Standard for Product Complaint Handling **(b)(4)**, Standard for Complaint Investigation Process **(b)(4)**, Complaint Investigation Activity **(b)(4)**, BPV Complaint Handling System, **(b)(4)**, and **(b)(4)**, Complaint Investigation Procedures, **(b)(4)** do not include adequate instructions for ensuring that complaints involving a device or device component provided by a supplier are adequately evaluated for root cause of the alleged device failure and that appropriate corrective action is implemented with your suppliers.
b. Complaint **(b)(4)** for a G2 Filter, embolization of a detached filter arm with associated areas of hemorrhage and necrosis in the right lung was filed as a

malfunction Medical Device Report [MDR] and should have been filed as a death. The following complaints were filed as malfunctions and should have been filed as serious injuries: Complaint **(b)(4)**, Eclipse Filter, detached filter limb resulting in pericardial effusion and cardiac catheterization; **(b)(4)**, G2 Express Filter, broken filter and surgical intervention; **(b)(4)**, Denali Jugular System, detached filter arm embedded in IVC wall with filter retrieval; **(b)(4)**, G2 Filter, detached filter limb in renal vein with IVC wall perforation and blood thinner treatment; **(b)(4)**, G2 Express Filter, IVC perforation and aneurysm; **(b)(4)**, G2 Filter, abdominal pain with filter legs protruding through IVC wall and percutaneous removal; **(b)(4)**, G2 Filter, abdominal pain with filter legs perforating IVC wall, partial retrieval and residual filter leg fragment embedded in IVC wall.

c. Complaints **(b)(4)** and **(b)(4)** report at least 10 patients who were exposed to scheduled retrieval surgical procedures to remove an IVC filter that were not successful. However, these complaint files do not document sufficient information to allow for adequate complaint investigation and disposition, including, but not limited to, MDR determination. For example, the complaints do not include information regarding prolonged or repeated surgery that may have occurred as a result of failed attempts to remove the filters, information regarding why the filters were scheduled to be removed and potential complications related to leaving them in the patient due to failed removal, and/or if any additional drugs or anesthetics had to be supplied to the patients.

We find that your responses dated December 17, 2014, January 15, 2015, February 18, 2015, March 16, 2015, April 17, 2015 and May 6, 2015 from Mr. Jason J. Gaede, Vice President Plant Operations, C.R. Bard Inc., Queensbury, NY and your responses dated January 26, 2015, February 26, 2015, March 26, 2015, April 24, 2015, and May 22, 2015, from Mr. Steve S. Williamson, President, Bard Peripheral Vascular, a Division of C.R. Bard, Tempe, AZ do not adequately address these deficiencies. For example, your January 26, 2015, response states that you made clerical errors and that you opened a CAPA to track training and determination of root cause with corrective and preventive actions. Your response is inadequate and does not assure that your complaint handling system reviews and evaluates complaints adequately. Additionally, the revised complaint procedures provided with your initial responses do not include adequate corrections to complaint investigation procedures with regards to the above stated deficiencies. Your follow-up responses do not address any corrections for complaint handling deficiencies. Your responses also state that all actions have been implemented with respect to the violation and that your firm considers your response to be complete.

Quality System Regulation Violations at the Queensbury, NY facility

4. Failure to validate, with a high degree of assurance and approve according to established procedures, a manufacturing process that cannot be fully verified by subsequent inspection and testing, to ensure the process will continue to meet specifications as required by 21 CFR 820.75(a).

a. Specifically, IVC filter cleaning, to include removal of chemical processing contaminants, has not been validated for IVC Filters to include Simon Nitinol Filters, Eclipse Filters and Denali Filters. For example, production of Denali Filters requires

the use of several processing agents, including, but not limited to the following: nitric acid, methanol, sulfamic acid solution, thermo quench salt, glycolic acid, citric acid, and/or hydrofluric acid. The cleaning processes for IVC filters are not validated or otherwise verified to demonstrate that the above substances are reduced to acceptable levels during routine processing under worst case conditions. Therefore, your manufacturing process was not validated with a high degree of assurance and approved according to established procedures, nor were the process results fully verified by subsequent inspection and test, as 21 CFR 820.75(a) requires.

b. Your firm's own Process Qualification (PQ) Final Report **(b)(4)**., dated May 29, 2013, states that a 100% inspection plan is necessary for all failed predefined acceptance criteria during process validation. In particular, the PQ Final Report defines process capability acceptance criteria for Denali Filter Part **(b)(4)** dimensions of C, D, L, M, G, N, W, F, T, U and the radial force functional test to be a CpK greater than or equal to 1.33 as a requirement to validate the process. Your process qualification failed to meet this predefined acceptance criteria for these filter dimensions and functional test. Therefore, according to your own manufacturing process validation document, 100% inspection for verification of these specifications on each lot of product is required to mitigate your failed process validation. However, your firm has not ensured 100% inspection of dimensions N, W, F, G and M, which lacked validation. Your firm has also not conducted adequate subsequent process validation studies to eliminate this requirement. As a result, your manufacturing process was not validated with a high degree of assurance and approved according to established procedures, nor were the process results fully verified by subsequent inspection and test, as 21 CFR 820.75(a) requires.

We find that your responses dated December 17, 2014, January 15, 2015, February 18, 2015, March 16, 2015, April 17, 2015, and May 6, 2015, are not adequate for the following reasons:

• With regard to your promised corrections for IVC filter cleaning lacking process validation, we find your response partially adequate. We acknowledge your firm's actions to date associated with the CAPA you opened in response to this observation, **(b)(4)**. We acknowledge that you reviewed 510K submission data for the Denali Filters, conducted recent cytotoxicity testing for Denali Filters and revised your Process Validation procedure, **(b)(4)**., to specifically include the requirement of validating cleaning processes for components or devices that undergo contact with processing agents. We acknowledge your progress to date validating the cleaning processes for Denali Filters manufactured by both of your suppliers and Simon Nitinol Filters; however, this data will need further review during a follow-up inspection to verify adequacy of actions taken. We also acknowledge your performance of exhaustive extraction testing for the Denali Filters manufactured by one of your suppliers; however, the other supplier of these filters uses a different manufacturing process, processing agents, and equipment. Because of these differences, we recommend that you perform exhaustive extraction testing for Denali Filters manufactured by this supplier to ensure no residuals are present on these devices. Additionally, your firm has stated it is no longer manufacturing the Eclipse Filters as of 9/8/14; however, your firm has not indicated plans regarding the stored inventory of these devices and continues to market them in the United States. Your response to date does not indicate corrective action for these devices that may still be in inventory and/or may still be distributed.

• With regard to your promised corrections relating to process validation of your Denali Filter Part **(b)(4)** dimensions of F, N, W, G and M, we find that your response is not adequate. Your Process Qualification (PQ) Final Report **(b)(4)**., dated May 29, 2013, states that a 100% inspection plan is necessary for all failed predefined acceptance criteria during process validation. In particular, the PQ Final Report defines process capability acceptance criteria for Denali Filter Part **(b)(4)** dimensions and/or functional tests of C, D, L, M, G, N, W, F, T, U and Radial Force to be a CpK greater than or equal to **(b)(4)** as a requirement to validate the process. This predefined acceptance criterion was not met. Consequently, your firm conducted a retrospective analysis to change this original process validation criterion. You state your firm retrospectively analyzed data and determined that dimensions N and W may stay on AQL 0.65 limited inspections because the analysis demonstrated a 95/99.9% confidence level. However, your rationale for changing the original process validation acceptance criterion for dimensions N and W is not adequately supported.

Further, you have not been successful at validating the manufacturing process with respect to dimensions F, G and M, which failed predefined acceptance criteria. Your firm has not provided adequate data to support that these dimensions have been 100% inspected for every lot of product manufactured, as required by your firm's own manufacturing process validation document, PQ Final Report **(b)(4)**. And lastly, the corrective actions proposed as part of CAPA **(b)(4)** are in progress, and will need verification of implementation upon completion during a future inspection. For these reasons, your responses dated December 17, 2014, January 15, 2015, February 18, 2015, March 16, 2015, April 17, 2015, and May 6, 2015, are inadequate.

5. Failure to establish and maintain procedures for acceptance of incoming product and to inspect, test or otherwise verify incoming product as conforming to specified requirements as required by 21 CFR 820.80(b).

Specifically, based on your Process Qualification (PQ) Final Report **(b)(4)**., dated May 29, 2013, process capability acceptance criteria of CpK greater than or equal to **(b)(4)** for Denali Filter Part **(b)(4)** dimensions C, D, L, M, G, N, W, F, T, U and the radial force functional test were not met. As a result, these dimensions and/or functional tests were to remain on a 100% inspection plan during manufacture at your supplier in order to be accepted into inventory. However, your firm accepted supplier lot numbers **(b)(4)** of Denali Filter Part **(b)(4)**, which your supplier inspected with an AQL 0.65 sampling plan for dimensions N, W, F, G, and M, rather than 100% inspection. Your firm also accepted supplier lot numbers **(b)(4)** and **(b)(4)** of Denali Filter Part **(b)(4)**, inspected by your supplier with an AQL 0.65 sampling plan for dimensions N and W, rather than 100% inspection. Your procedures for acceptance of incoming product, including Inspection Plan IP **(b)(4)**., were not adequately established and maintained to verify that incoming product conformed to your specified requirements of 100% inspection plan for dimensions N, W, F, G, and M. As a result, you failed to inspect, test or otherwise verify incoming product as conforming to your specified acceptance requirements, as required by 21 CFR 820.80(b).

We find your responses dated December 17, 2014, January 15, 2015, February 18, 2015, March 16, 2015, April 17, 2015, and May 6, 2015, partially adequate. Your responses do not clarify whether acceptable corrective actions have been taken with the above stated lots of Denali Filter components that lacked 100% inspection of dimensions N, W, F, G, and M to ensure your

specified acceptance requirements have been met for these accepted lots. Your response does not contain evidence that the above stated lots indicating an AQL 0.65 sampling plan for dimensions F, G and M were in fact inspected at 100% for F, G and M. Further, your response does not contain evidence that your supplier's AQL 0.65 sampling plan is an adequate inspection, test, or verification of incoming product for dimensions N and W. We acknowledge your firm has opened CAPA **(b)(4)** to address systemic corrections to this observation; however, outputs of this CAPA are still in progress and will need to be verified during an FDA inspection of your firm.

6. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR 820.50. In particular, 21 CFR 820.50(a) requires that each manufacturer establish and maintain requirements, including quality requirements, that must be met by suppliers, contractors, and consultants.

Specifically, your Process Qualification (PQ) Final Report **(b)(4)**., dated May 29, 2013, documented that process capabilities for filter dimensions C, D, L, M, G, N, W, F, T, U and the functional test radial force, as defined under section 7 Acceptance Criteria – Process Qualification of this report, were not met for all dimensions and functional tests. The PQ Final Report states that because the process capabilities were not met, these filter dimensions and functional test should remain on a 100% inspection plan at your supplier until such time that objective evidence indicates process capability has been demonstrated. However, your supplier failed to inspect the product on a 100% inspection plan for filter dimensions N, W, F, G and M, and process capability was not demonstrated through objective evidence. For example, from approximately May 11, 2013 to August 5, 2013, your supplier of Denali Filter Part **(b)(4)** provided you with a Certificate of Compliance for supplier lot numbers **(b)(4)**. These certificates documented the supplier did not conduct 100% inspection for filter dimensions N, W, F, G and M. Your firm did not begin to address the issue with your supplier until approximately August 5, 2013 during an audit of your supplier, which was after most of these 23 lots were accepted into your inventory and used in the manufacture of finished Denali IVC Filter devices.

In the PQ Final Report **(b)(4)**., your firm establishes purchasing control procedures as required by 21 CFR 820.50(a). These procedures include continued 100% inspection by your supplier for process capabilities that were not met with regards to filter dimensions C, D, L. M, G, N, W, F, T, U and for process capabilities that were not met with respect to the functional test radial force. However, when filter dimensions N, W, F, G, and M failed your established process capabilities, your supplier did not conduct 100% inspection. By failing to maintain adequate supplier control procedures (i.e., by failing to ensure 100% inspection was conducted for failed process capabilities), your firm violated 21 CFR 820.50(a), which requires that manufacturers establish and maintain requirements that must be met by suppliers.

Additionally, when suppliers are placed on Limited Approved status, such as your supplier of the Denali Filter Part **(b)(4)**., you do not have adequate instructions in your supplier control procedures, including but not limited to **(b)(4)** Supplier Performance Management Rev. 05, to re-evaluate suppliers to ensure that the supplier is better able to meet your specifications.

We find that your responses December 17, 2014, January 15, 2015, February 18, 2015, March 16, 2015, April 17, 2015, and May 6, 2015, appear adequate, but are still in progress and will need to be verified during an FDA inspection of your firm.

MDR Violations at the Tempe, AZ facility

Our inspection of your Bard Peripheral Vascular facility located at 1625 W. 3rd St., Tempe, AZ also revealed that the Cardiovascular intravascular filter, (IVC Denali Filter Delivery System), is misbranded under Section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information regarding the devices that is required by or under Section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 803 - Medical Device Reporting. Significant deviations include, but are not limited to:

7. Failure to submit a report to FDA no later than 30 calendar days after the day that your firm received or otherwise became aware of information, from any source, that reasonably suggests that a device that your firm markets has malfunctioned and this device or a similar device that your firm markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur, as required by 21 CFR 803.50(a)(2).

For example, Complaint numbers **(b)(4)** describe a malfunction of your firm's device, which is classified as a long term implant. Your firm did not rule out that the reported malfunctions would not be likely to cause or contribute to a death or serious injury, if it were to recur. Therefore, an MDR should have been submitted for each of the referenced complaints.

We reviewed your firm's responses received by the FDA, including the January 26, 2015, response, and conclude the response is not adequate. Your firm did not submit MDRs for the above referenced complaints and failed to justify why such malfunctions would not be likely to cause or contribute to a death or serious injury, if the malfunctions were to recur.

8. Failure to obtain and submit to the FDA information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters; and if unable to submit complete information on a report, failure to provide a statement in your firm's report explaining why required information was incomplete and the steps taken by your firm to obtain the information, as required by 21 CFR 803.50(b)(2) and 21 CFR 803.50(b)(3).

Specifically, your firm submitted 15 MDRs to the FDA, which did not identify the patient's "Age at Time of Event" or "Date of Birth" in Blocks A2 and A4, respectively, of the FDA Form 3500A. In addition, your firm did not include an explanation of why the required information was not provided and the steps taken to obtain such information.

We reviewed your firm's responses received by the FDA, including the January 26, 2015, response, and conclude the response is not adequate. Although the FDA has received supplement reports for some of the MDRs, we have not received supplements for all.

The eMDR Final Rule requiring manufacturers and importers to submit electronic Medical Device Reports (eMDRs) to FDA was published on February 13, 2014. The requirements of this final rule will take effect on August 14, 2015. If your firm is not currently submitting reports electronically, we encourage you to visit the following web link for additional information about the electronic reporting requirements:

http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm (http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm)

If your firm wishes to discuss MDR Reportability criteria or to schedule further communications, it may contact the Reportability Review Team by email at:

ReportabilityReviewTeam@fda.hhs.gov (mailto:ReportabilityReviewTeam@fda.hhs.gov)
Your firm should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties. Also, federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation violations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (including any systemic corrective actions) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen (15) business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter.

Your written response should be sent to the Food and Drug Administration; Attention:

Dr. Raymond W. Brullo
Compliance Officer, Los Angeles District

U. S. Food and Drug Administration
19701 Fairchild
Irvine, CA 92612

A copy of your written response should also be sent to:

LCDR Catherine M. Beer
Compliance Officer
U. S. Food and Drug Administration
One Winners Circle, Suite 110
Albany, NY 12205

If you have any questions about the content of this letter please contact: Dr. Raymond W. Brullo at (949) 608-2918.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Form FDA 483, Inspectional Observations (FDA 483), issued at the close out of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

Sincerely yours,

/s/

Alonza E. Cruse, Director
Los Angeles District

Cc:

Kevin J. Bovee
Director of Quality Assurance
C.R. Bard, Inc.
289 Bay Road
Queensbury, NY 12804

Jason J. Gaede
Vice President, Plant Operations
C.R. Bard, Inc.
289 Bay Road
Queensbury, NY 12804

Mark M. Walaska
Staff Vice President Manufacturing
Bard Peripheral Vascular, Inc.
1625 W. 3rd St.
Tempe, AZ 85281

Steve S. Williamson
President
Bard Peripheral Vascular, Inc.
1625 W. 3rd St.
Tempe, AZ 85281

Patricia Christian
Vice President, Quality, Regulatory and Medical Affairs
C.R. Bard, Inc.
730 Central Ave.
Murray Hill, NJ 07974

Gin Schulz
Vice President, Corporate Quality Assurance
C.R. Bard, Inc.
730 Central Ave.
Murray Hill, NJ 07974

More in 2015 (/ICECI/EnforcementActions/WarningLetters/2015/default.htm)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Los Angeles District
Food & Drug Administration
19701 Fairchild
Irvine, CA 92612

December 8, 2015

Mr. Timothy M. Ring
Chairman and Chief Executive Officer
C.R. Bard Inc.
730 Central Ave.
Murray Hill, NJ 07974

Dear Mr. Ring:

We received your correspondence dated August 3, 2015, September 3, 2015, October 5, 2015, and November 20, 2015 in which your firm responds to the violations addressed in the Warning Letter (#27-15) issued to you on July 13, 2015. Your firm's responses have been made part of the official file for your firm and will be considered with other records there.

After completing our evaluation of your firm's responses, we have the following general comments:

Glen Falls Operations (New York)

- With respect to your responses to Warning Letter violation items 4 and 5, regarding validation/verification and incoming inspection of Denali Filter components received from your supplier, the actions being taken with respect to NNI appear to be adequate. However, from a systemic standpoint, your response does not indicate any follow through actions that may or may not be taken with respect to the same filter components received from your other supplier, Memry. While this supplier was not indicated to be the source of any issues cited on the Warning Letter, we would recommend that any actions taken to improve the process with NNI and receipt of these filters with 100% verification and proper inspection also be taken or reviewed if needed to be taken with Memry.

- With respect to your response to Warning Letter violation item 3c, we want to note with you that it is important to make a record of all attempted correspondence and actual correspondence with a complainant and have it readily available for FDA review during an inspection. In the event that the desired conclusive information cannot be obtained from a complainant, having a concise record of correspondence attempts and information may assist your firm with proper complaint handling and compliance with 21 CFR Part 820.198 and 21 CFR 803 requirements.

- Additionally, your firm provided a HHE regarding the Denali Filters in distribution that cannot be confirmed as being 100% verified for all filter dimensions as Attachment 4-20 in your August 3, 2015 response. It should be noted that no major issues were noted during my review of this document. However, full evaluation of your HHE for adequacy would require FDA Medical Expert review. At this time this is not being requested, however this action may be taken should the agency deem this necessary at a later date.

Bard Peripheral Vascular (Arizona)

- With respect to your response to Warning Letter violations items 3, 7 and 8 regarding complaint handling and medical device reporting [MDR] per your teleconference meeting with the Medical Device Policy Branch on October 26, 2015, please note the following. Please be prepared to address these issues in any follow-up inspection and, at this time, provide a response to these items:

[redacted]

You are responsible for ensuring your establishment operates in compliance with the Food Drug and Cosmetic Act, the Medical Device Reporting Regulation (21 CFR Part 803), the Current Good Manufacturing Practice Regulation (21 CFR Part 820) and any additional applicable regulations. The completion and impact of your promised corrective actions to date and any further corrective actions will be evaluated during our next inspection of your facility.

Sincerely,

Raymond W. Brullo -S

Dr. Raymond W. Brullo
Compliance Officer
FDA, Los Angeles District

Catherine M. Beer -A

LCDR Catherine M. Beer, USPHS
Compliance Officer
FDA, New York District

cc:

Kevin J. Bovee
Director of Quality Assurance
C.R. Bard, Inc.
289 Bay Road
Queensbury, NY 12804

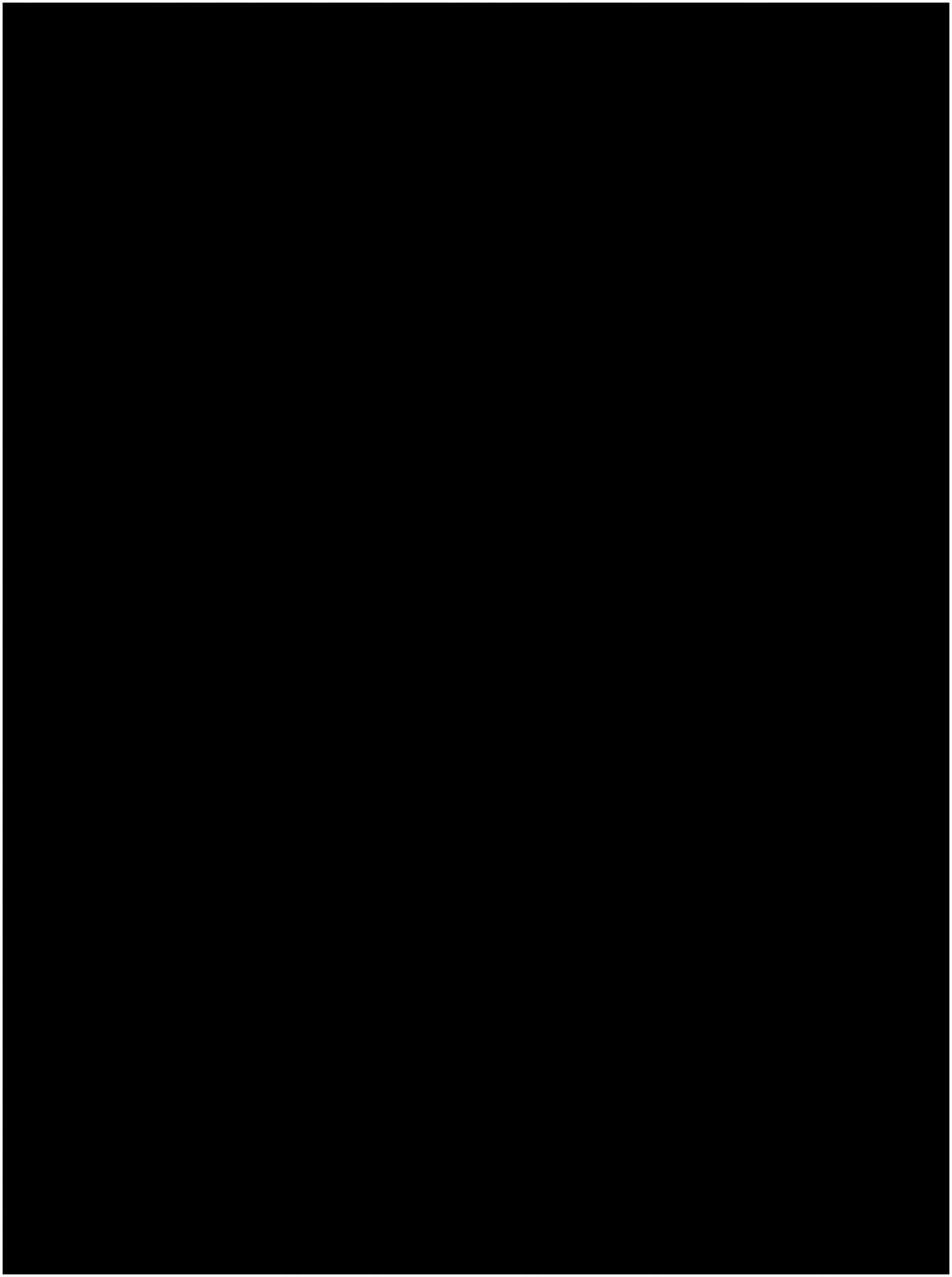
Jason J. Gaede
Vice President, Plant Operations
C.R. Bard, Inc.
289 Bay Road
Queensbury, NY 12804

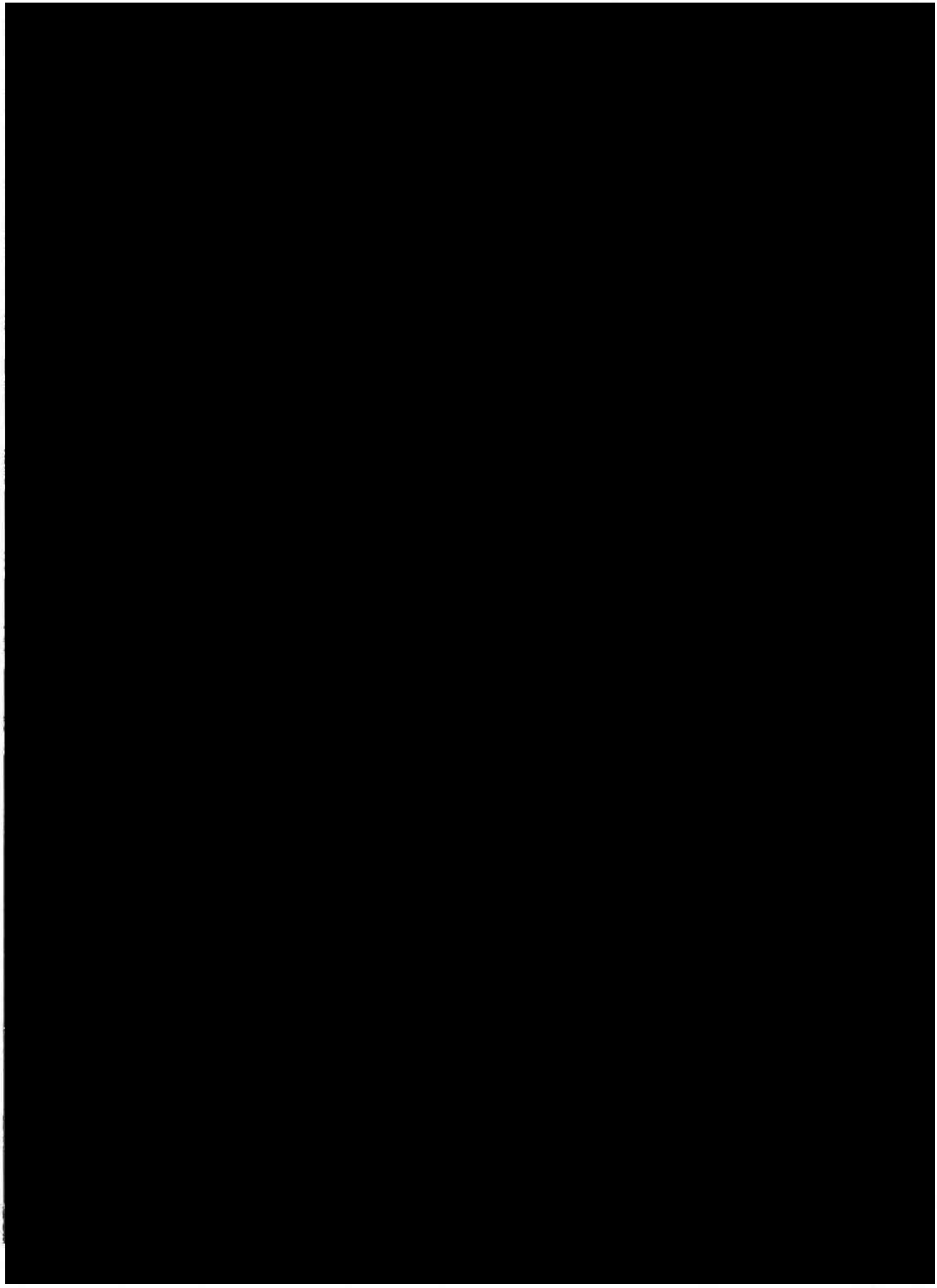
Mark M. Walaska
Staff Vice President Manufacturing
Bard Peripheral Vascular, Inc.
1625 W. 3rd St.
Tempe, AZ 85281

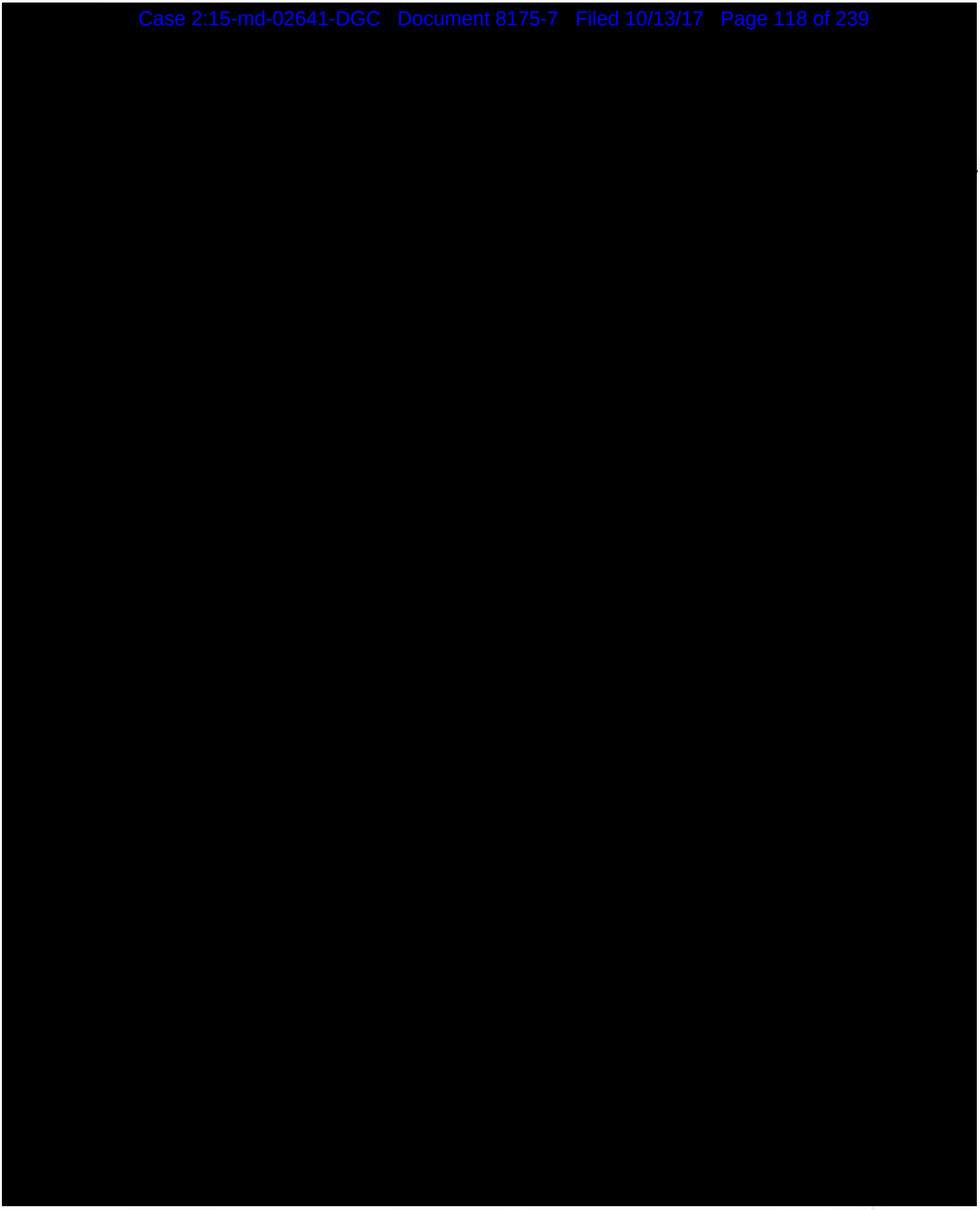
Steve S. Williamson
President
Bard Peripheral Vascular, Inc.
1625 W. 3rd St.
Tempe, AZ 85281

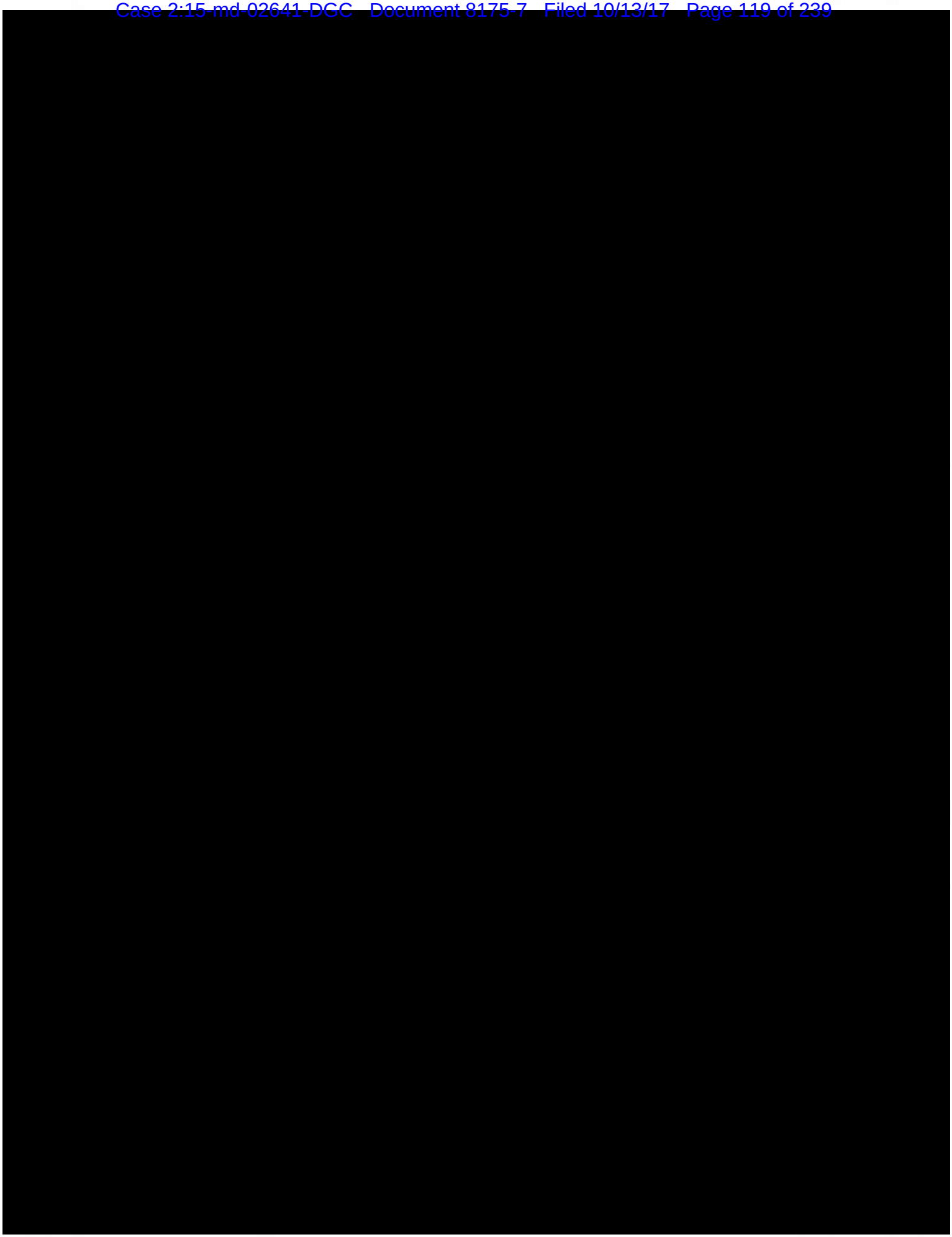
Patricia Christian
Vice President, Quality, Regulatory and Medical Affairs
C.R. Bard, Inc.
730 Central Ave.
Murray Hill, NJ 07974

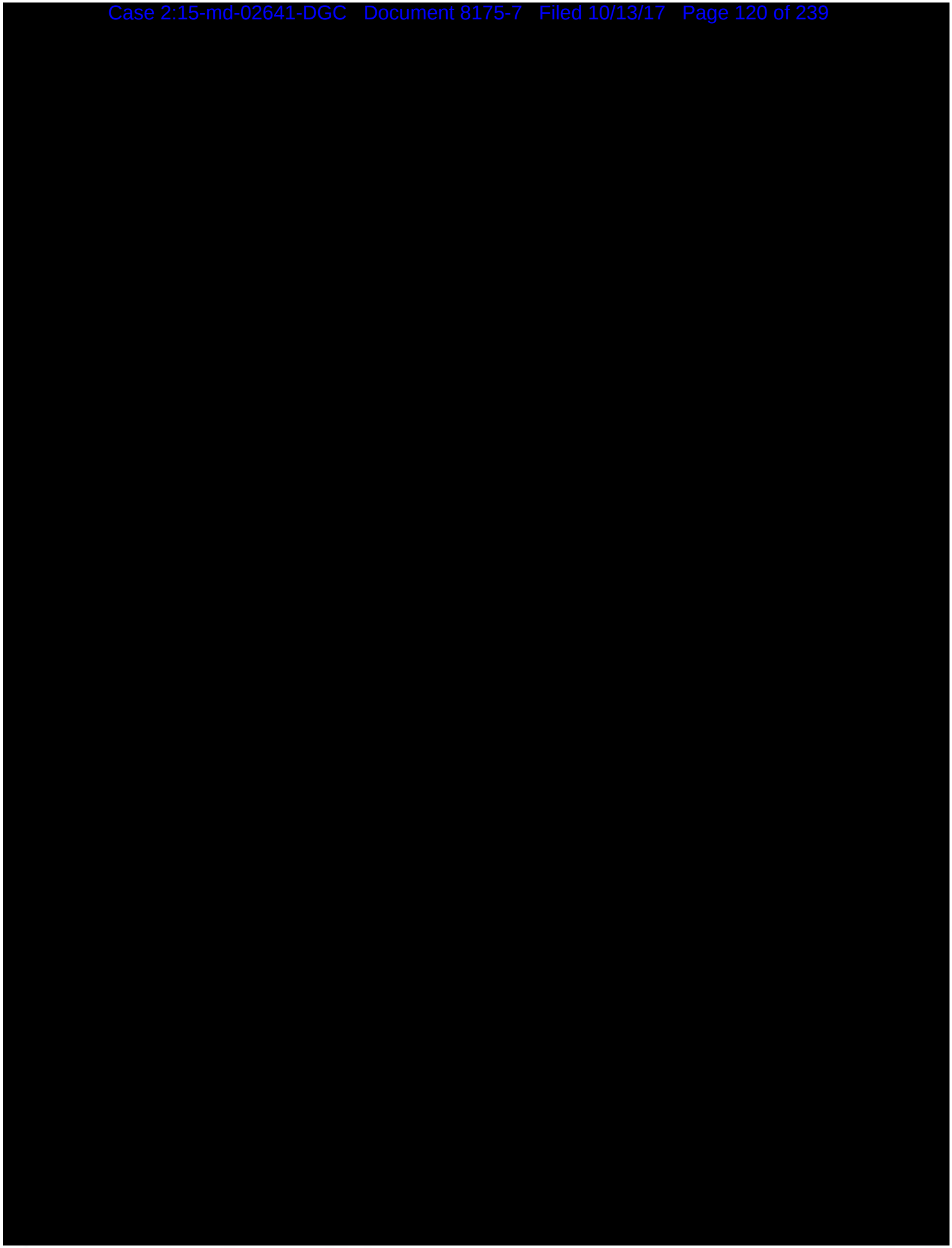
Gin Schulz
Vice President, Corporate Quality Assurance
C.R. Bard, Inc.
730 Central Ave.
Murray Hill, NJ 07974











Schedule 22 – Corrosion Test Results of the Modified Recovery Filter by CC Technologies

CC Technologies
a DNV company

CC TECHNOLOGIES, INC.
Research Department

5777 Frantz Road
Dublin, OH 43017-1386
U.S.A.
Tel: (614) 761-1214
Fax: (614) 761-1633
www.dnv.com
www.cctechnologies.com

December 7, 2007

Bard Peripheral Vascular, Inc. - Interventional
Mr. Mike Randall
PO Box 1740
Tempe, AZ 85280 - 1740

Re: Corrosion Testing of Set 4 Vena Cava Filters (Project No.: 81174891)

Dear Mike:

This is our Final Report on the above-referenced project. In October, 2007, Bard submitted a set of Nitinol vena cava filters for corrosion testing. The objective of the testing was to evaluate the corrosion susceptibility of the filters using the cyclic potentiodynamic polarization (CPP) test technique per ASTM F2129 - 06[1].

BACKGROUND

[redacted]

[1] "Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices," ASTM International, Conshohocken, PA.

At CC Technologies, each filter in a group was assigned an identification number for tracking purposes, e.g., Group A – 1233-1 through 1233-4. Figure 1 shows a typical filter from each of the six groups.

Bard specified phosphate buffered saline (PBS) solution, from the list in the ASTM standard, for CPP testing of the filters. CC Technologies procured PBS in the form of tablets from VWR Scientific Co., Catalog No. EM-6500. The catalog listed composition of the solution, produced on dissolving a PBS tablet in 100 mL deionized water, as follows: 137 mM sodium chloride, 2.7 mM potassium chloride, and 10 mM sodium phosphate dibasic/potassium phosphate monobasic buffer. This composition is similar to that given in the ASTM Standard. The bottles received from VWR were labeled, "PBS Tablets (Phosphate Buffered Saline)", OmniPur®, Lot No. 0957B017.

EXPERIMENTAL DETAILS

Test Technique

The ASTM Test Method F2129-06 is an accelerated corrosion test in that it electrochemically forces the passivity of the test specimen to break down (i.e., undergo pitting, crevice corrosion, or "transpassive" dissolution) and then allows for re-passivation to proceed as the stimulus is gradually removed. The product of the test is a CPP curve, which is a plot of the applied stimulus (electrode potential) against the specimen's response (current). A CPP curve is usually presented as a plot of the electrode potential vs. current density on a semi-logarithmic scale.

The electrochemical parameters, or results of interest, which can be extracted from a CPP curve are: (a) rest potential – E_r, (b) breakdown or critical pitting potential – E_b, (c) vertex potential – E_v, (d) protection potential – E_p., and (e) final potential – E_f. Refer to the ASTM standard for the significance of the various parameters.

Two derived parameters of practical interest are "breakdown or pitting margin" and "pitting protection margin", which are defined as $E_{bm} = E_b - E_r$ and $E_{pm} = E_p - E_r$, respectively. These two parameters, however, are not parts of the ASTM standard. The E_{bm} provides a measure of the resistance of the test specimen to localized forms of corrosion attack in the test environment. The greater the value of the E_{bm}, the greater is the resistance of the specimen to the localized forms of corrosion. Similarly, a high value of the E_{pm} implies relative ease of repassivation following localized breakdown of the specimen. In general, a value of 200 mV for the E_{pm} is considered a minimum for the practical use of the specimen in the service environment that was simulated by the test solution.

If passive film break down does not occur during the forward polarization scan up to E_v, no protection potential is produced during the reverse scan. After the passive region, a gentle rise of the current up to E_v may signify transpassive dissolution of the alloy or the onset of the oxygen evolution reaction. Both of these reactions are not relevant to the corrosion performance of the implant devices.

Test Procedure

[redacted]

Group A Filters

[redacted]

Group E Filters

[redacted]

[redacted]

The entire set of filters will be returned by FedEx on December 7, 2007. Please feel free to contact us if you have any questions.

Sincerely,

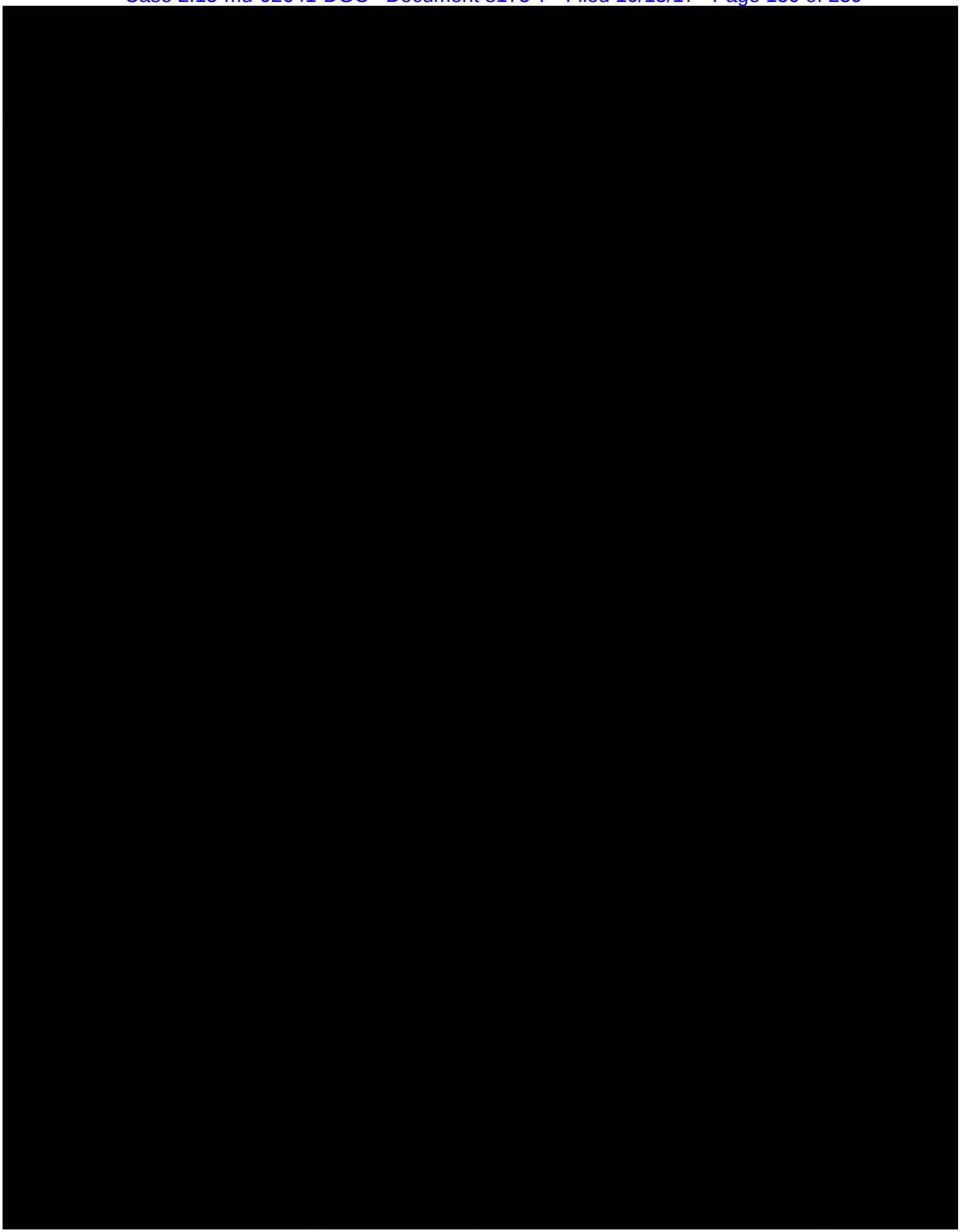
For CC TECHNOLOGIES, INC. (A DNV COMPANY)

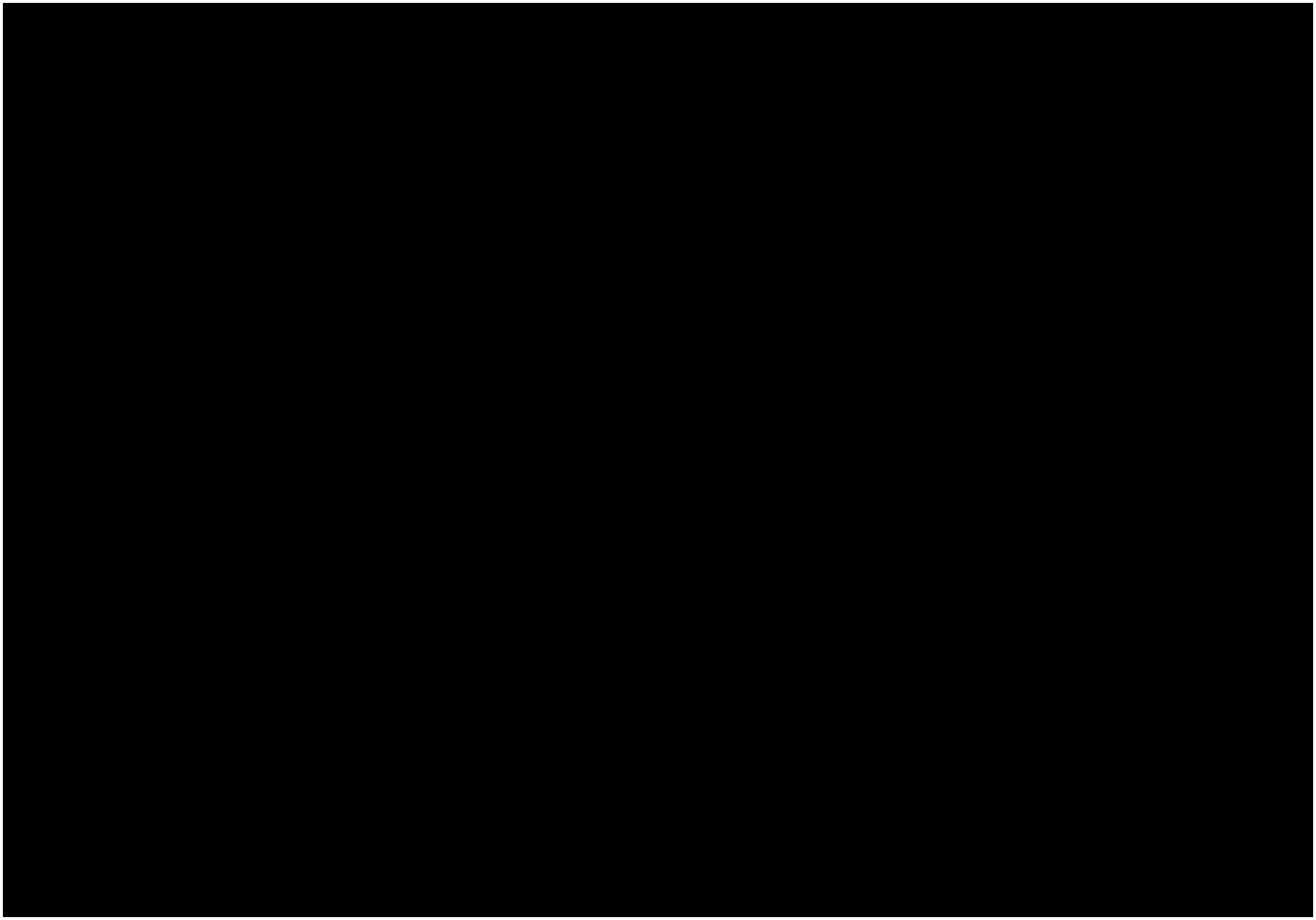
Arun K. Agrawal, Ph.D.
Senior Project Manager

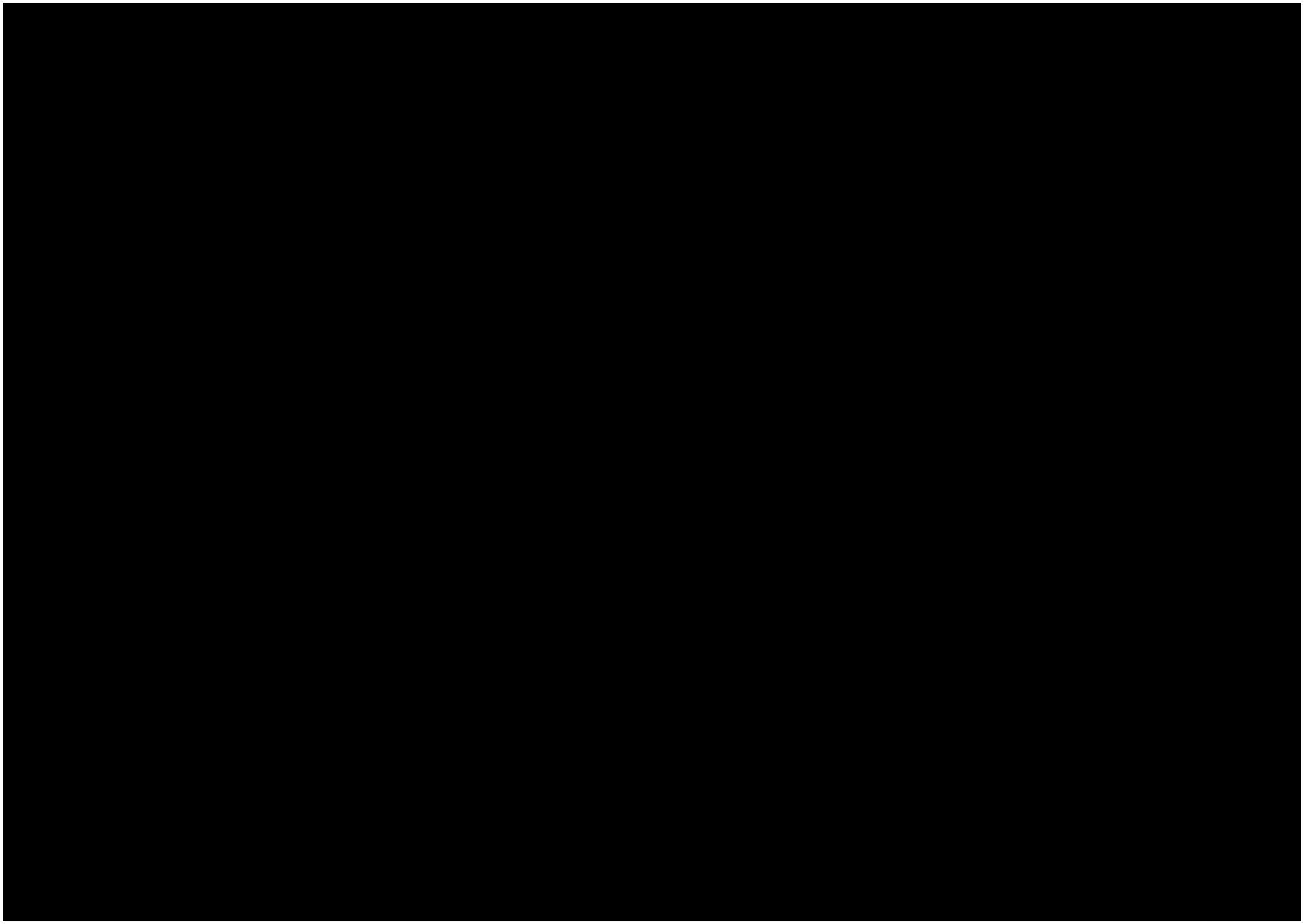
C. Sean Brossia, Ph.D.
Director of Research

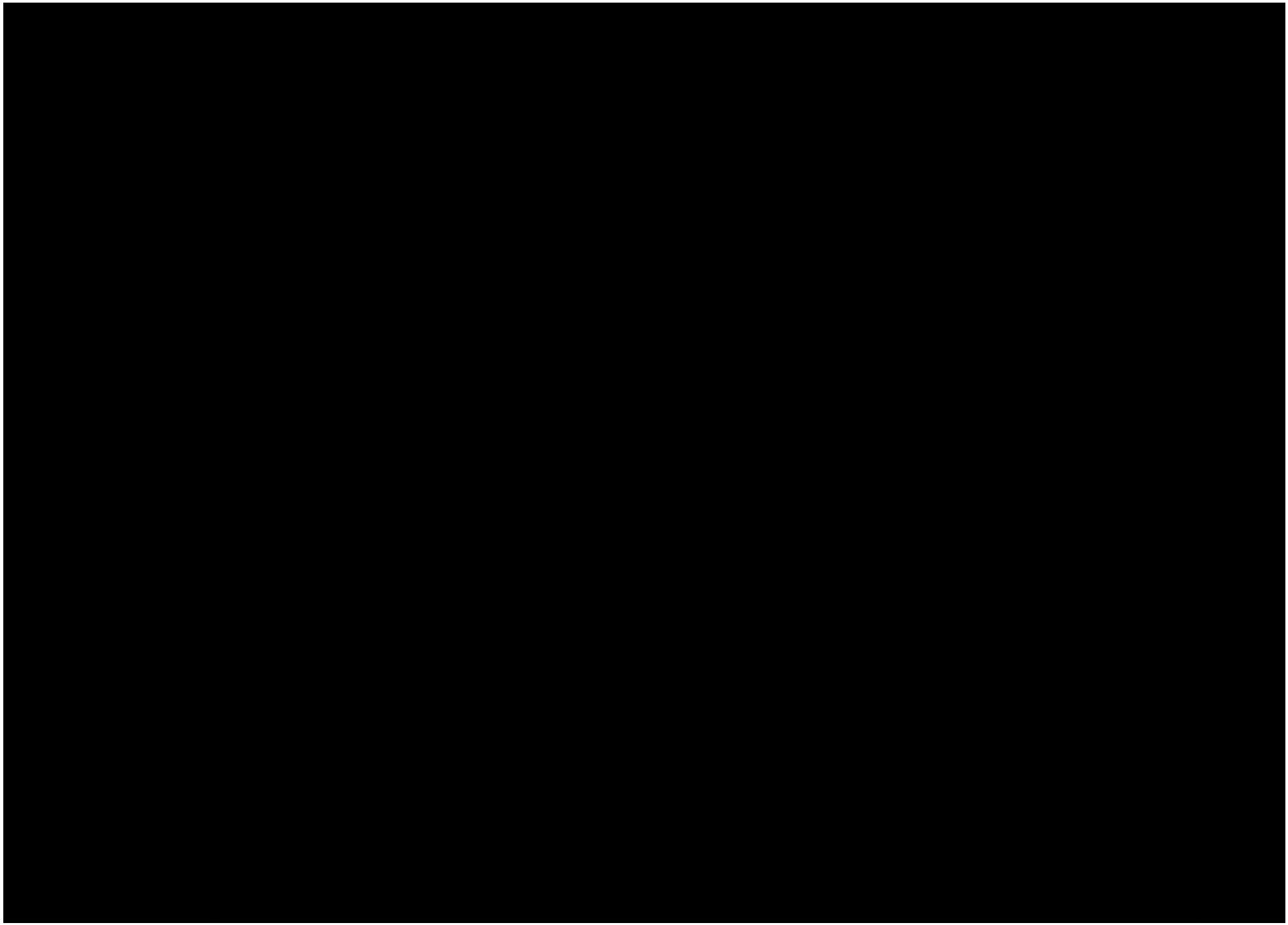
Attachment:/dm

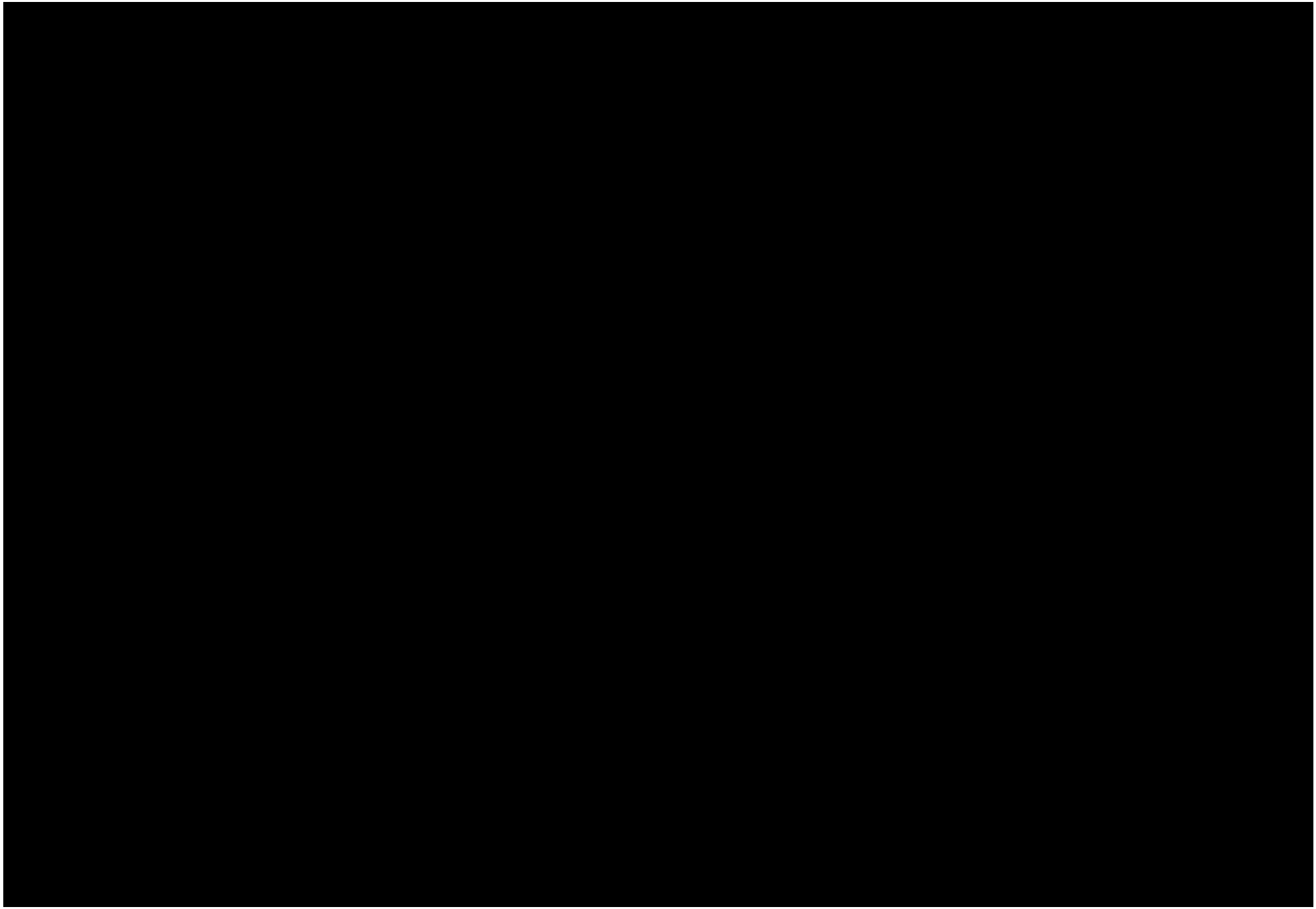
Table 1. Results of the CPP tests of vena filters of Set 4, Group A through Group F, in PBS solution at 37 °C.

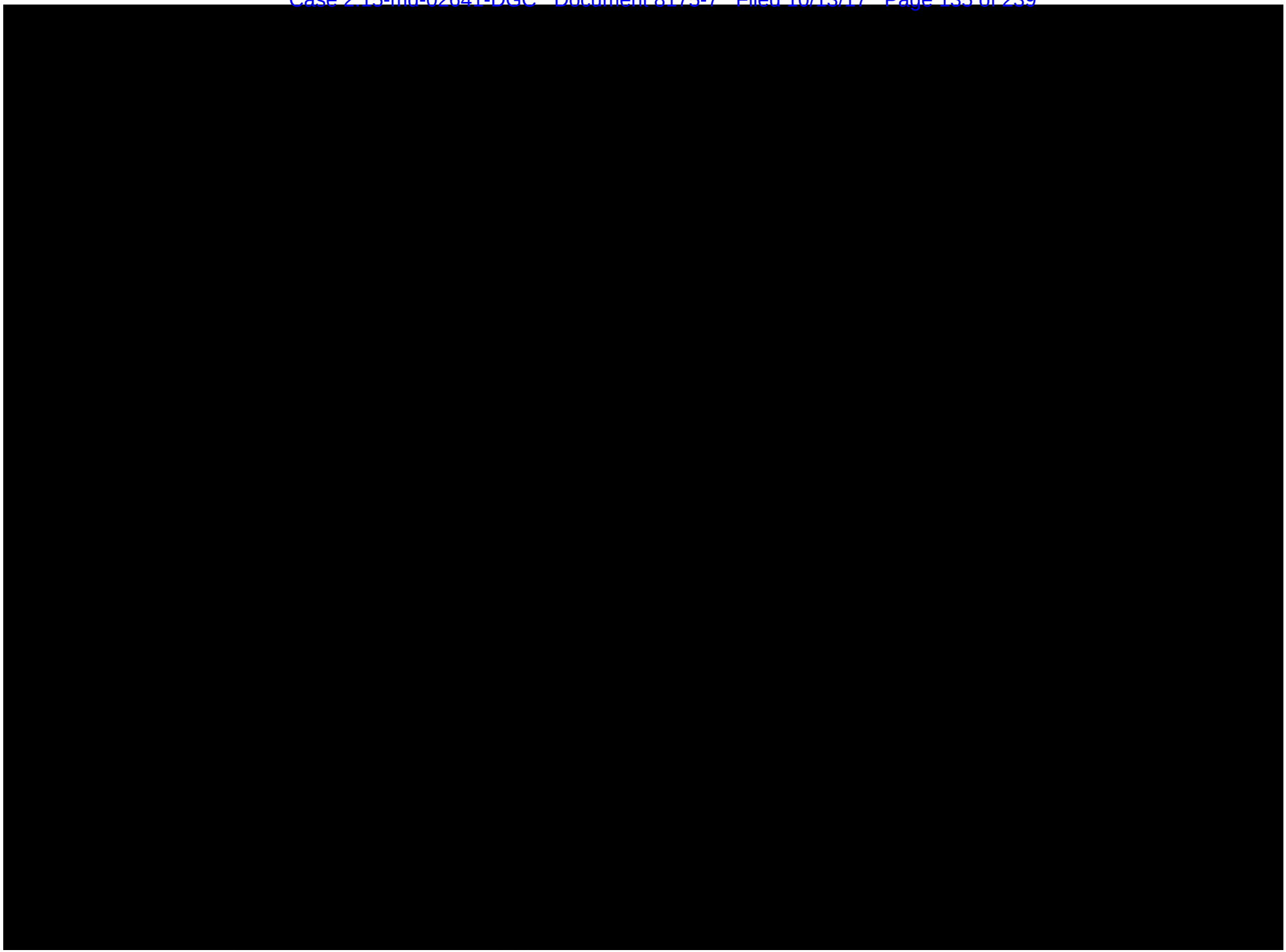


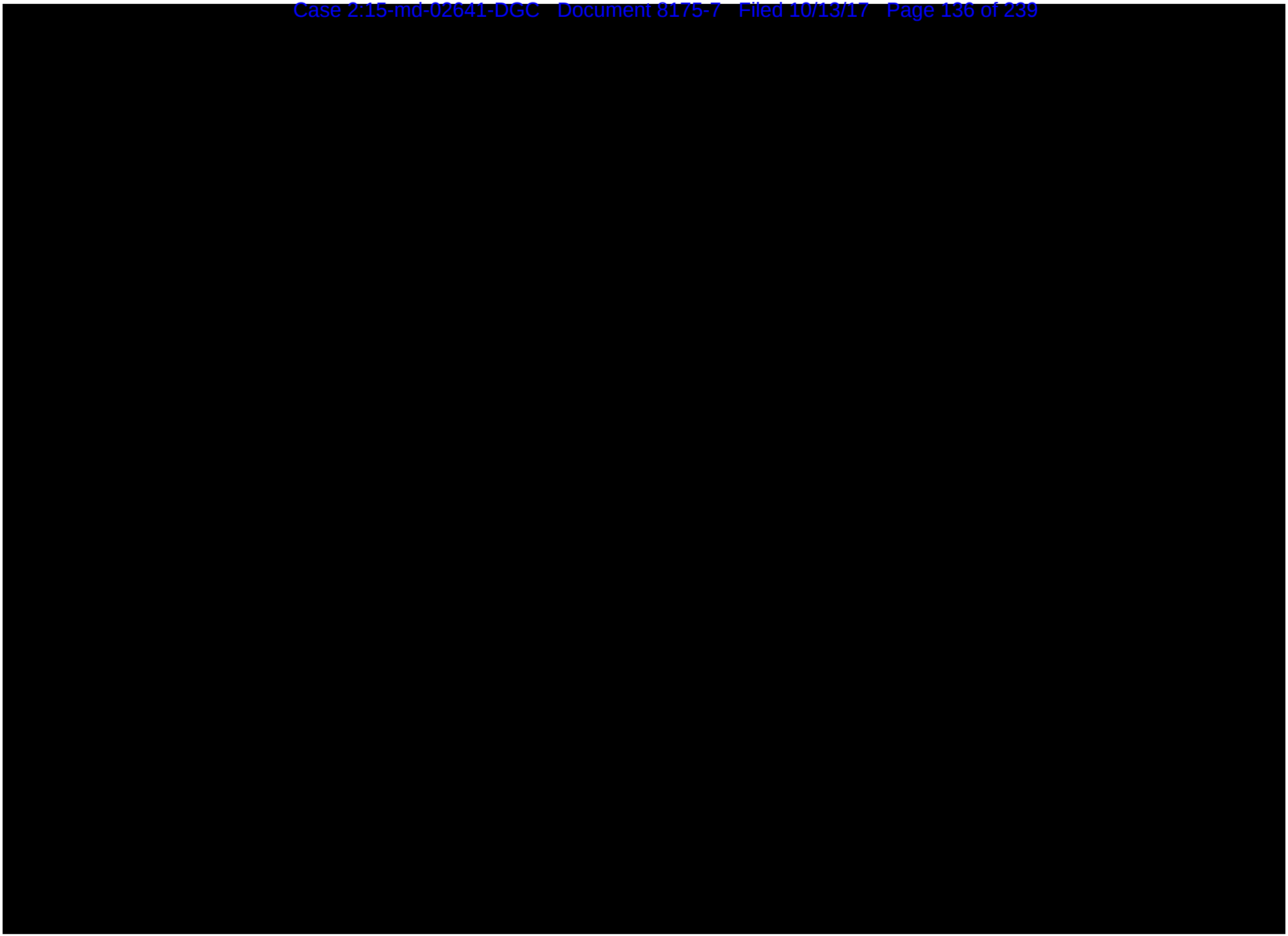












CC Technologies
a DNV company

CC TECHNOLOGIES, INC.
5777 Frantz Road
Dublin, OH 43017-1386
United States

Tel: (614) 761-1214
Fax: (614) 761-1633

August 31, 2007

Employee Training Documentation

Dr. Kathy Krajewski earned her bachelors and doctorate degrees in Materials Science and Engineering at The University of Michigan and the Georgia Institute of Technology, respectively. For her graduate studies, she focused on characterizing the electrochemical corrosion mechanisms of the Ag-Pd alloy system in artificial saliva to determine the suitability of using Ag-Pd alloys for dental applications. In addition, she also investigated the effects of proteins on the corrosion behavior of Ni-Ti (Nitinol) alloys for biomedical applications. Both studies involved utilizing DC polarization measurements to characterize fundamental corrosion parameters.

At CC Technologies, Inc. Kathy has read and understood ASTM F2129 – 06, "Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices". She has successfully conducted tests using the above standard, under the supervision of Dr. Arun Agrawal. She is qualified to conduct the above type of electrochemical corrosion tests independently.

Employee,

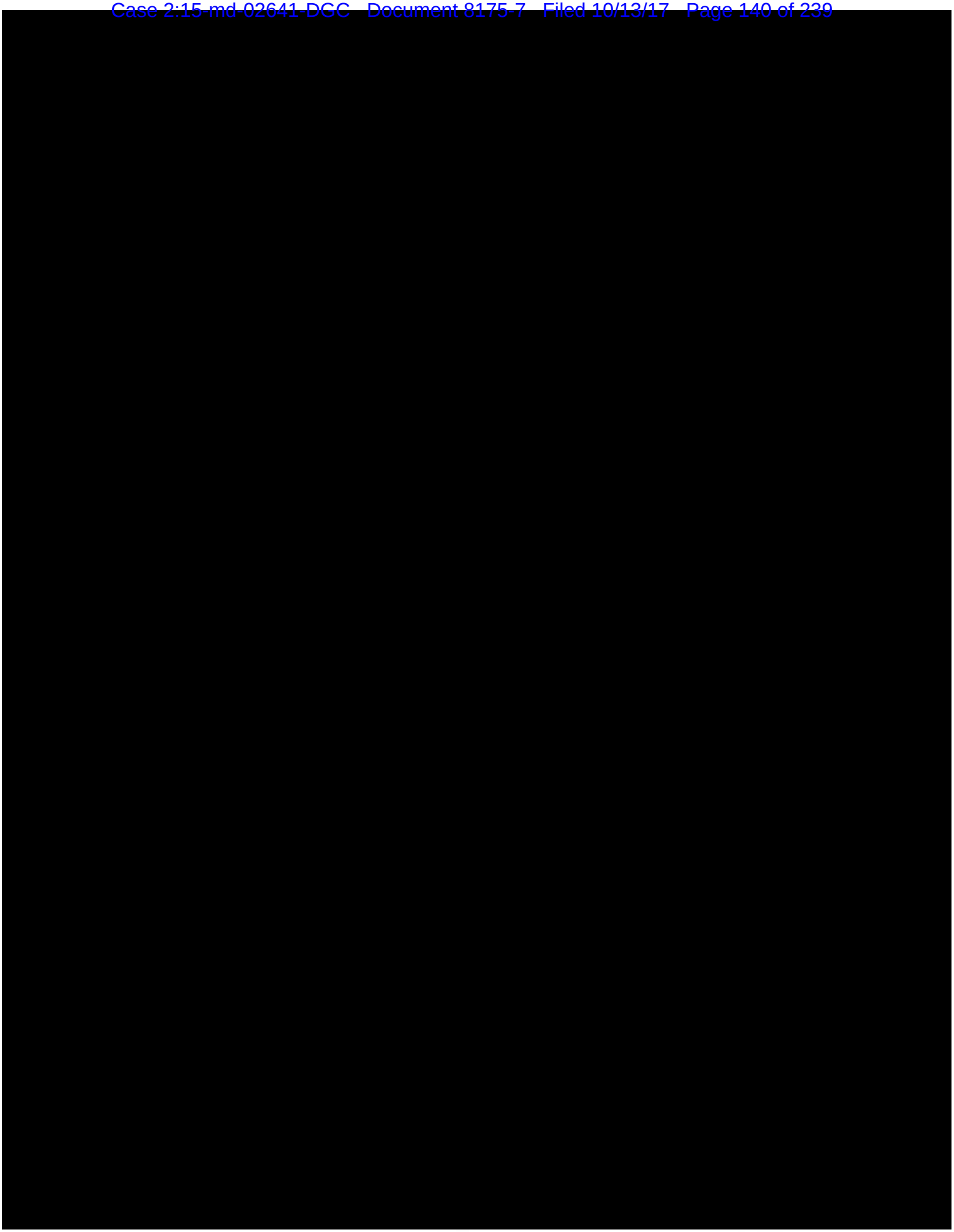
Kathy Krajeswki, Ph.D.
Senior Engineer

Trainer,

Arun K. Agrawal, Ph.D.
Senior Project Manager

AKA:/dm

Schedule 23 – Photomicrograph



Schedule 24 – Comparative Corrosion Results with other Competitive Filters

Schedule 24 – Comparative Corrosion Results with Other Competitive Filters

Date	Bates	Name	Summary
12/17/2007	BPV-17-01-00180333-340	Corrosion Testing of Set 1 Cordis Optease Filters	[redacted]
12/17/2007	BPV-17-01-00180323-330	Corrosion Testing of Set 2 Greenfield Filters	
12/17/2007	BPV-17-01-00180344-351	Corrosion Testing of Set 3 Cook Gunter Tulip Filters	
12/7/2007	BPV-17-01-00180307-322	Corrosion Testing of Set 4 Vena Cava	

		Filters	[redacted]
12/17/2007	BPV-17-01-00180299-306	Corrosion Testing of Set 5 Vena Cava Filters	

Schedule 25 – Testimony Concerning Signature on Recovery 510(k)

Schedule 25 – Testimony Concerning Signature on Recovery 510(k)

Deposition/Date	Page: Line	Question	Answer
Kay Fuller Deposition 01/11/2016		**Questions by Howard L. Nations**	**Answers by Kay Fuller**
	Page 129:18-25	Q. Who would normally sign the submission letter?	A. Well, in this case, because I was assigned to be the regulatory person on this team, and it had been told that I was doing the 510(k) submission, it typically would be me.
		Q. Okay. And did you sign this letter accompanying submission?	A. No, I did not.
		Q. Why not?	
	Page 130:1-16		A. I was concerned about the things we've been discussing.
		Q. Specifically?	A. Specifically, that I didn't feel like we had adequately addressed the fracture failure mode, and put in an adequate corrective action. And I was most concerned also that the 10-year simulated cycle testing had been conducted on a pre-sterilized device. I was most concerned that this product might have problems and might have some failure modes that could hurt people.
		Q. All right. Did you ever at any time authorize anyone else to sign this document in your behalf?	A. No, I did not. **Exhibit 127 - BPV-17-01-00057959**
	Page 131:13-25 – Page 132:1-8	Q. Okay. Let me direct your attention over to page… BPV- Number **57963**…what is this document?	A. It appears to be the Truthful and Accuracy Statement.
		Q. Okay. Now, we discussed before	A. No, I did not.

		what that is, and did you sign this?	
		Q. And who did sign it?	A. Carol Vierling.
		Q. And why did you not sign it?	A. Because I take the signing of the Truthful and Accuracy Statement very seriously. It's my responsibilities to make sure that everything we're submitting to the Agency is truthful and accurate, and that we haven't omitted pertinent facts. And I was uncomfortable signing that. It's really the first time and only time in my career I was not comfortable signing that in an application to the FDA.
	Page 157:13-23	Q. Let me hand you what's been marked Exhibit132. And ask you if you can recognize this.	A. This looks like a copy of a Bard Peripheral Technologies authorization for market release Recovery Filter, it has identifiers of that project, so –
		Q. Is that the signature page for the fact book, or can you tell? MR. NORTH: Objection to the form.	THE WITNESS: I would -- I would probably, to be certain, I'd probably need more information.
	Page 158:1– 160:2		A. But it does look like it has the management -- the level of approvals that would be required, including the project team. And the management approvals and other approvals. So -- but I'm not positive that this is the fact book. This is authorization for market release, so I'm not sure that this is the fact book.
		Q. Did you sign the fact book?	A. It's my recollection that I did not.
		Q. Did you -- do you recall whether you were not asked to sign the fact book or did you refuse to sign the fact book?	A. I was asked to sign it. It actually sat on my desk, in my office. And my recollection is I went on -- I took a few days off, I think this was around the holiday period in December.
		Q. It was.	A. And the book was fairly large on my desk, in my office. And I had indicated I was not going to sign it until we had these key test reports that I was looking for. Such -- what that means is even though we might have gotten received -- or we had received the 510(k) clearance from the FDA to sell 24 the product with the permanent indication, you can't release the

			product until the fact book is signed off, and so forth. And I had indicated that if we weren't going to do some of the testing I was concerned about, that I wasn't comfortable signing off on the fact book. I went on -- I took a few days off, and when I came back, the fact book was not on my desk. And I later learned that Mary had gone ahead and signed off on the fact book. That's my recollection.
		Q. Okay. So in your role as the regulatory liaison, would you have normally signed the transmittal letter to the -- of the submission to the FDA, the Truthfulness and Accuracy Verification, and the fact book?	A. Yes. MR. NORTH: Objection to the form.
		Q. Did you sign any of those three?	A. No.
		Q. Just for clarification, on the transmittal letter with the submission, your name is signed to that letter, as you saw?	A. The name "Kay Fuller" is in cursive writing, yes.
		Q. Is that your signature?	A. And I just want to clarify, you're speaking to the letter that is included in the 510(k) 2 submission?
	Page 160: 3-10	Q. Yes.	A. So I don't call that a transmittal letter. That is a -- included in the 510(k) submission.
		Q. Oh, okay.	A. That the original was submitted to the FDA.
		Q. Right. Okay.	A. I did not sign that. That is not my signature.
	Page: Line	**Questions by Richard North**	**Answers by Kay Fuller**
	Page 271:3 - 272:1-3	Q. You've been handed 145, it's a document you've seen before, I think another version of it is marked. And that is the letter that went with the 510(k), dated June 10 of 2002?	A. I believe it was July 10 of 2002.

		Q. I'm sorry, July 10 of 2002 to the FDA. Correct?	A. Yes. That's what it appears to be.
		Q. Now, you told us earlier that you refused to sign this letter?	A. I had made it clear I would be very uncomfortable submitting the 510(k).
		Q. Did you know the 510(k) was going out?	A. I knew that it was being routed for signature, and I knew the plan was to submit it. We had had a draft letter that was dated July 8th, and so it was routing for final review.
		Q. And did you know that the draft l letter said to contact you for -- by telephone if they had any questions?	A. Yes.
		Q. So even though you declined to sign this letter, you knew that the letter was going to advise the FDA to contact you?	A. Yes. I was -- had been designated as the FDA contact person for this submission.
	Page 272:24 – 273:1-25	Q. Did you know that there was going to be a signature line for you on this letter?	A. Yes.
		Q. So even though you would not agree to sign it, you knew there would be a signature line for you?	A. I knew that I had seen the draft with both of our signature lines.
		Q. And did you ever tell anyone "Do not sign my name to that letter"?	A. Absolutely not.
		Q. So you testified earlier this morning that you never authorized anybody to sign that letter, but now you are telling us, too, that you never told anybody not to sign that letter on your behalf?	A. Oh, I -- I apologize. I would like to reanswer the question. I misunderstood the question. What is the question?
		Q. Did you tell anybody -- you knew	A. Yes.

		that the draft letter had a signature line for you?	
		Q. And did you tell -- tell anybody to take that signature line off for you?	A. No.
		Q. Did anyone tell you that someone in the Covington facility was going to sign your name?	A. No. And I would like to just add that in our industry we're trained that our signature has authority, and if someone were going to sign on my behalf, the proper way to do that would be to sign your own name on behalf of the person that you're signing for.
	Page 275:16-21	Q. Did you put in writing that you would not -- that you did not feel comfortable signing that letter?	A. I certainly made it clear verbally. I – I don't recall whether I documented that in writing or not. I don't recall.
	Page 282: 16 – 284:3	Q. After you refused to sign the cover letter, according to your testimony, Bard could have submitted the letter with only Ms. Vierling's signature line and been in full compliance with the regulations, couldn't it?	A. Certainly. Two signatures are not required to submit a 510(k) application.
		Q. And Bard did not need your signature on that letter to proceed with its submission, did it?	A. The only reason that my name, my signature would be needed is to designate in that cover letter who the FDA is required to contact on behalf of the company relating to that submission during the review process at the FDA.
		Q. But that's up to Bard who is going to be the contact person, isn't it?	A. Well, it's up to the team, yeah.
		Q. I mean, the FDA doesn't have a regulation that says the person at the medical device company that holds the position of senior regulatory affairs specialist must be the person signing the Truthfulness and Accuracy Statement?	A. That's correct.
		Q. And, in fact, I've seen one – these statements signed by people in your	A. Me too.

		position. I've seen them signed by Ms. -- people in Ms. Vierling's position. And I've seen them signed by people who are vice presidents –	
		Q. -- of regulatory affairs?	A. Me too. Absolutely.
		Q. And it's just whoever the company wants to designate?	A. It has to do with who the FDA is to contact relating to that submission, and yes, it's required to be an employee of the company, and it doesn't state the title of the name of the person that signs that document.
	Page 284:10-17	Q. Didn't you find that a little unusual that you wouldn't sign the letter, but you knew it was going to the FDA identifying you as the contact person?	A. I was a little curious how it was that this was going to be submitted without my signature, because it had been added to the draft cover letter. So I was curious how they were going to do that.
	Page 294:1-295:21	Q. Let's go through this and I've got a follow-up couple questions, and then we'll be starting something new anyway.	A. Okay.
		Q. This is an August 6 e-mail from Aymee Berry to various people and copied to Mary Edwards. Right?	A. Yes.
		Q. Now, look at the second page of this. At the very bottom, that's an e-mail from you to Mary Edwards. Correct?	A. The second page.
		Q. At the very bottom. Kay Fuller at IMPRA?	A. Yes.
		Q. "Hi, Mary, can you or Mary take care of this for now? I can only do it after the 510(k) is submitted to the Agency." And this is written August or -- that has a strange date?	A. Yes, it does.

		Q. The date right above it, though, is July 9 of 2002. Correct?	A. July 9? Yes.
		Q. So this is in the same time frame. Right?	A. Appears to be, yes.
		Q. So from the time this 510(k) for permanent indication was submitted in -- on July 10 of 2002, in the following weeks, you were already hard at work on the second 510(k) for retrievable indication. Correct?	A. Drafting it, yes.
		Q. And you were having multiple meetings with the team?	A. Yes.
		Q. And you were generating weekly e-mails to, at least weekly, to Ms. Edwards advising her of the process?	A. Of the progress, yes.
		Q. Yeah. And you were exchanging e-mail communications with the team. Correct?	A. Yes.
		Q. And in not one of these documents we've seen have we seen any mention or any implication of the concerns you said you had prior to July 10 of 20 2002, have we?	A. That's correct.
Carol Vierling Deposition 05/26/2016	**Page: Line**	**Questions by Howard L. Nations**	**Answers by Carol Vierling**
	Page 82:4 – 17	Q. And that's what I was going to ask you. You are aware that NBC ran a national news story concerning Kay Fuller's allegations that her signature was forged on the FDA submittal, correct?	A. Yes.

		Q. And I'm assuming somebody from Bard called you up after that, is that right?	A. They -- actually, I got a text from one of my friends. "I saw your name on NBC news." So, yes, I was made aware of it.
		Q. And then that's what led to the call from Patty Christiansen?	A. Yes.
	Page 171:7-23	Q. That's your signature, right?	A. Yes.
		Q. And that's dated July 9th, 2002?	A. Yes.
		Q. And what was the date of the 510(k) submission?	A. I don't have that. July 10th.
		Q. July 10th?	A. July 10th, 2002.
		Q. I thought it was July 8th?	A. The cover letter says the 10th.
		Q. Oh, okay. Did you ever become aware of anyone at Bard or IMPRA becoming critical of Kay for not being a team member or for any other aspect of her work on the Recovery filter?	A. No, not at all.
	Page 174:12 – 177:7	Q. And you are aware Kay Fuller testified she did not sign that letter, right?	A. I'm aware of that, yes.
		Q. Okay. Did Kay Fuller sign this letter?	A. No, she didn't, but I have to tell you there is another copy of this letter that I have seen. This is it looks like the library copy, which is the copy that would have been kept in our files, but I've seen another copy of this letter where it is signed differently.
		Q. Well, let me ask you: Is this copy the one that went to the government, Kay Fuller's signature?	A. No, it's not.

		Q. Whose signature is it?	A. It's mine.
		Q. Did Kay Fuller give you permission to sign it?	A. I don't know if she did or not. She certainly didn't tell me not to sign her name to the submission.
		Q. Well, when you sign somebody else's name, isn't it the proper practice to write "Kay Fuller by Carol Vierling" or "on behalf of Carol Vierling" to indicate that it is not the person signing it but that it's you signing it on their behalf?	A. Yes, on the letter that I believe went to FDA, the other letter, I signed it Carol Vierling for Kay Fuller.
		Q. When did you last see that letter?	A. When we prepared for the deposition.
		Q. Is that yesterday?	A. I don't know if it was yesterday or a couple of weeks ago. I don't remember.
		Q. So you signed one Carol Vierling for Kay -- Kay Fuller by Carol Vierling and another one you just signed Kay Fuller?	A. The copy that went to FDA I signed Carol Vierling for Kay Fuller. The library copy, which is the copy we kept on file, I just signed it Kay Fuller. It didn't really matter. I didn't even have to sign this copy. It is just our library copy.
		Q. When you signed Kay Fuller, were you attempting to sign -- to make it appear that it was her signature?	A. No
		Q. The -- but I think you told me Kay Fuller did not give you permission to sign it, is that right?	**A. She neither gave me permission nor told me not to sign her name.**
		Q. Shouldn't you obtain the person's permission to sign their name on their behalf?	A. I clearly signed on behalf -- I said Carol Vierling for Kay Fuller.
		Q. But if you say Carol Vierling for Kay Fuller, that implies that she is giving you permission, doesn't it?	A. Yes, she certainly did not tell me do not sign my name. And I really could have left her name off completely because the purpose of the letter was to inform FDA that she would be the contact person to give her telephone number and her fax number.

		Q. But you didn't pick up the phone and call Kay and say, Is it okay if I sign this for you?	A. I don't remember if I did that or not.
		Q. So if she said that that didn't occur, you'd have no basis to disagree with her, would you?	A. I wouldn't.
	Page: Line	**Questions by Robert Boatman**	**Answers by Carol Vierling**
	Page 177:20 – 178:4	Q. I did have one question, and that is, I assume nobody told you that Kay Fuller had said because of her concerns over the failure investigation she would not sign either the transmittal letter or the truth and accuracy statement, is that true?	A. No one told me that, that's correct.
		Q. And if somebody had told you that, you would not have signed on her behalf, is that right?	A. Absolutely not.
	Page: Line	**Questions by Ms. Daly**	**Answers by Carol Vierling**
	Page 210:12 – 215:8	Q. And if you look at the -- at the top here, is there anything that you notice at the top of the letter that tells you anything about the source of this document?	A. I see an FDA/CDRH/ODE stamp, so it appears that it was received by FDA on June 11th, 2002. **Exhibit FDA_PRODUCTION_00001577-78**
		Q. Can you look at that again on the date?	A. I'm sorry.
		Q. June 11th?	A. Yes. July 11th.
		Q. Yeah, okay. So let's look at the second page of this, if we could. On the second page of this, let's start with the production number, it's at	MR. NATIONS: 1578 just for the record.

		the bottom, this shows it as a production number of 000158. There is also a number, let me just point out to you, 0244 that's stamped on it.	
		Q. I'm sorry. 1578. There is also a stamped number 0244. Do you see that?	A. Yes.
		Q. If you go back to the first page, do you see a stamp number down at the bottom as well?	A. Yes.
		Q. 0243?	A. Yes.
		Q. All right. So 0243 and 0244, correct?	A. Yes.
		Q. All right. So looking at the next page, does this appear to be the same as the letter – the second page, the same as the second page of the letter that you told us was the library copy?	A. No, it's not.
		Q. All right. And what is different about it?	A. This one on the Kay Fuller signature line I signed, "Carol Vierling for Kay Fuller." On the library copy, I signed it "Kay Fuller."
		Q. Is that also your signature under the second signature that says "Carol Vierling"?	A. Yes
		Q. Now, were you and Ms. Vierling – Ms. Fuller working in the same offices at the time that the submission went in on July 10, 2002?	A. No. She was located in Tempe, Arizona. I was in Covington, Georgia.
		Q. Was it unusual to sign for somebody else who was in a different office if you were sending something out	A. Yes. And if I had known it was going to be an issue, I would have left her name off the letter. My intent was to inform FDA at the very last part of the second page that if they have any

		from your office? MR. BOATMAN: Object to the form.	questions, please contact Kay Fuller, with her telephone or fax number, because I wasn't going to be there to answer any follow-up questions. She would, so they needed to know her contact information.
		Q. Did you intend to suggest to the FDA that Kay Fuller herself had signed this document?	A. No, otherwise I wouldn't have signed it Carol Vierling for Kay Fuller.
		Q. Was there any Bard requirement that you were aware of or FDA requirement that Kay Fuller's name had to be on this cover letter?	A. There was no requirement.
		Q. You put her on there because you were pointing out that you told them who their contact person is after you leave, correct? MR. BOATMAN: Object to the form.	A. Yes.
			A. And I note her title.
		Q. Now, you've already testified that you were never told by Kay Fuller or anybody else that she was refusing to sign this letter, correct?	A. That's correct.
		Q. Had Ms. Fuller told you that she would not sign this cover letter, what actions do you think you would have taken?	A. I would have asked her why. If she had told me it was because she had concerns about the safety of the filter, that she didn't feel the 510(k) should be submitted, we would have talked about that as a team, and if we couldn't resolve her concerns, we'd take it up the ladder.
		Q. And when you say "take it up the ladder," where would the ladder take you?	A. It would take us through Mary Edwards up to Susan Alpert if we needed it to.
		Q. So did you feel that you had a direct ability to communicate with Susan	A. Yes. She had a very open door policy. Anyone could contact her at any time.

		Alpert?	
		Q. Okay. And this is the Susan Alpert who had been at FDA?	A. Yes.
		Q. Shortly before coming to Bard?	A. Yes
		Q. All right. Did you forge Ms. Fuller's name on this letter?	A. No, I did not.
		Q. On the library copy of the letter?	A. No, I did not.
		Q. Did you ever forge any document for Ms. Fuller?	A. No.
		Q. Did you ever forge a document period in your entire time at Bard?	A. No, I have -- I did not.
Mary Edwards Deposition 08/19/2016	**Page: Line**	**Questions by Howard L. Nations**	**Answers by Mary Edwards**
	Page 30:1 – 34:18	Q. This is the letter of July 10th of 2002, that accompanied the submission of the 510(k). Do you recall that?	A. Yes. **Exhibit 375 BPV-TRIAL-EXHIBIT-0002 and 0003**
		Q. Okay. On page 2, Carol Vierling has acknowledged that she signed Kay Fuller's signature, as shown here. Did you authorize Carol Vierling to sign Kay Fuller's signature to the submission letter?	A. I wouldn't have known. I -- I'm not familiar with -- or how or why this is here, to be honest with you. Is it is not uncommon, I have to tell you, is because Carol at this point was still in Georgia. We were in Arizona, so it wouldn't be uncommon to go ahead and sign for somebody who was in a different division. But I know that, you know, obviously, it is -- all questions would be directed to Kay, so I would assume -- I have no specific knowledge or memory of this because it's too long ago. But I can't imagine that Kay wasn't fully involved in this, and to my memory she was fully involved in the preparation of the submission. But Carol did the actual shipment of it, probably. But this was in the middle of the transition from -- peripheral group in Georgia joining the group in Tempe.

		Q. You said it was not unusual. Was there a specific protocol in place for one employee signing the signature of another to a document?	A. Not a procedure in place. I certainly had told people before that they could -- it's usually -- what would be done is it would be – it would have usually been like "Carol for Kay Fuller."
		Q. Okay. Was there an actual official –	A. No. No.
		Q. There was not an official protocol on that?	A. No, we all worked so closely together that, you know, we worked back and forth all the time for each other.
		Q. Were you consulted in any way by anyone about Carol Vierling signing Kay Fuller's name to that document?	A. No.
		Q. Did Kay Fuller ever have a conversation with you in which she advised you that she was not going to sign the document because she didn't agree with it?	A. Absolutely not. I mean, obviously, as it says here, is, "If you have any questions, contact Kay." I mean, this is just transition from one division to another. And Kay answered all the questions for the submission.
		Q. Why does it have Kay Fuller's signature line on there?	A. This was just the transition.
		Q. Actually, this was -- this was actually after the transition, because, if I recall correctly, Carol Vierling was supposed to leave on -- she gave her retirement notice as of June 30th of -- ten days earlier. Do you recall that?	A. No.
		Q. Okay. Was Carol Vierling asked by you or anyone else to stay on for the extra ten days after her resignation date for the purpose of signing this document?	A. I have -- I don't remember that far back. I would tell you that as dedicated as Carol was, it would not surprise me that -- and I have done this probably in every single one of my jobs, is complete work assignments, because she had an excellent relationship with the company. We held her in very high regard. So it would not surprise me that she would -- she would say, "I'll finish this, this last piece of work."

		Q. When did you first become aware that Carol Vierling had signed Kay Fuller's name to this document?	A. I had never become aware of it.
		Q. Okay.	A. And I have no knowledge of that, actually.
		Q. Now, you say that it is not unusual for one employee to sign for another. But this is a federal document. This is a federal submission. This is a submission that carries with it the truth and accuracy statement. Is there a protocol in place that, when you are submitting something to the federal government, to the FDA, that you deal with on a regular basis, that it should be signed by the person whose name is on it?	A. There is nothing nefarious here. It is -- and there is no policy. This was a really small group. We're only talking about five or six people who were doing regulatory affairs at this time. We worked very closely together. Carol was working with the rest of the team on this, and specifically in this transfer. You know, I have -- I would have no way to know that that wasn't Kay's signature, and certainly Kay never came to me and said, "Oh, my God. Somebody signed this for me," you know.
		Q. Did Kay ever raise any questions with you about the submission and her disagreement with parts of it?	A. No.
	Page 35:22- 42:20	Q. Okay. What you have in front of you is Exhibit 358.	A. Uh-huh.
		Q. And if you look over to the second page on this one, you will see that there is – the signature is different. This purports to be the same document. It is the July 10th submission letter with the 510(k), but this one is signed Carol Vierling, for Kay Fuller?	A. Uh-huh.
		Q. Do you know why there were two different documents, two different signatures?	A. All I can -- look down at the bottom of here and see that it's FOI, so that would normally mean freedom of information. This one has a stamp for CDRH, so this looks like this was the actual one that went with the submission. That's all I can -- you know,

			anything else would be... **FDA_PRODUCTION_00001577 and 00001578**
		Q. So then what was the previous one? What was 357, then? If this was -- if 358 is the one that was filed with the FDA, what was 357?	A. It could have been a file copy, you know, if you -- I really don't know.
		Q. An archived copy. Do you keep -- you keep an archive, obviously, of everything you submit to the FDA?	A. Bard absolutely does. I do not personally.
		Q. Well, I –	A. Yeah.
		Q. Yeah, when I say “you” there, I meant Bard.	A. Yeah.
		Q. So Bard actually has an archive?	A. They have a library copy.
		Q. And so the standard is that you copy what you submit to the FDA and keep it in your library?	A. Uh-huh.
		Q. Okay. If you could answer "yes" or "no" so that she can –	A. Oh, I'm sorry. I apologize on that. I'm usually better than that. Yes, that would be correct. You have an electronic copy and then you -- we normally had a printed-out desk copy, if you have it, or library copy.
		Q. Okay. So if this is an archived copy, the	A. A little bit of my own accent coming through.
		Q. And so the standard is that you copy what you submit to the FDA and keep it in your library?	A. Uh-huh.
		Q. Okay. If you could answer "yes" or "no" 357, why does it have a different signature than the file copy? Can you explain that?	A. No, I didn't create either one of these 4 documents, so no.

		Q. Well, within the protocols under your management as vice president, how would this happen?	A. This is the official copy, obviously, that went to the agency.
		Q. Right	
		Q. 358.	A. 358 is the copy that went to the agency, was I can see because of the stamps. Is -- 357, I would assume, those -- was an archived or a file copy. And those are -- those are those are normally run off, and they are working copies. If -- this isn't -- it wouldn't make me blink.
		Q. Wouldn't your archived copy, though, customarily just be a Xeroxed copy of the one filed with the FDA?	A. You are asking me to guess and speculate on this one.
		Q. Okay.	A. I mean; different companies have different 4 policies. Now we almost do everything electronically, so the electronic copies don't have any signatures on them.
		Q. If the -- okay. So I'm asking you specifically about Bard's policy under you in 9 July 10th of 2002. Was it the policy in filing an official document with the FDA to simply make a Xeroxed copy of that to keep in the archive so you would have an identical file in your archives that the FDA has?	A. We would have put a copy for the library copy. As far as the cover sheet, there was no specific policies or anything else that required that they be exact. I want to be careful in saying this, in that they were normally run off, is -- you would be making, you know, five to seven copies, you know. You know, they would go to -- there would be a working copy for the project. There would be a working copy for, obviously, regulatory affairs. We would usually put one in the library. And normally you would be just running the copies. This one was done by Carol. You would have to ask Carol. By this point it's just a copy that has gone into our files.
		Q. But isn't this misleading, to have a different copy in your archives than you actually filed with the FDA?	A. There is no response that I can give for that, because it -- if there had been a concern or anything at the time, is -- this should have come up the line, but there was nothing that this wouldn't have been concerning.
		Q. Well, it's concerning, if you look at your archive now and you want to	A. If Kay had come to me and said, "I'm concerned that somebody signed this for me," of course I would have been concerned. But

		see who signed this document, it would indicate that Kay Fuller signed the document; isn't that concerning?	there was -- there is - - as I said it earlier, there was nothing that would have been nefarious because this would have been just a file copy.
		Q. Yeah. But the point is, right now, today, if someone went into the Bard archive to see the July 10th, 2002, submission letter that went with the 510(k), wouldn't they be misled into believing that Kay Fuller signed that document because that's the only signature on there? MS. DALY: Object to the form.	
		Q. You may answer.	A. What I would do, if I was trying to know exactly what was filed with the agency, I would go through FOI, the same thing.
		Q. Yeah, but that's not the issue.	A. But that's the official copy. This is the only official copy. That's why I'm confused on what you are trying to get at.
		Q. Suppose Bard's -- but if someone subpoenas Bard's copy of this and they want to see who signed it without going through a FOIA, if they want to see Bard's copy of this, then they would be led to believe that Kay Fuller signed it because that's what the archive copy shows; is that correct?	A. Well, if you are led to believe it because you didn't go after the Freedom of Information copy, I guess you could say that. But this is the official record. This is the only official record, because the other one's simply a library copy.
		Q. But if you produced this document, being the 357, the one signed with Kay Fuller's signature, her name, if you produced that to a Court, wouldn't it appear to the Court that Kay Fuller signed that document? MS. DALY: Object to the form. Lack of foundation on what a Court	A. Yeah, I have no way to answer that. I really don't.

		would think.	
		Q. So to anyone subpoenaing Bard's records on this, what would they be led to believe with respect to who signed this document? MS. DALY: Same objection. What other people would believe. Lack of foundation.	
		Q. You may answer.	A. All I can tell you is -- personally, is just knowing the records, is I would go to what was actually filed. I wouldn't count on a file copy.
	Page: Line	**Questions by Robert Boatman**	**Answers by Mary Edwards**
	Page 221: 3-19	Q. And I think Mr. Nations asked you, but we have a document where -- several documents where Carol Vierling says her last day is June 30th and she stayed on until July 10th. You don't recall exactly why it is she stayed on?	A. Like I said, I have done the same thing in my career, where I have stayed on to finish a project, and you usually have a consulting agreement in place.
		Q. You don't -- the answer is so you don't know, you are guessing?	A. Yeah
		Q. But you don't believe it was because she had to sign the filter truth and accuracy because Kay Fuller wouldn't?	A. Absolutely not.
	Page: Line	**Questions by Ms. Daly**	**Answers by Mary Edwards**
	Page 277:9-282:10	Q. Did Ms. Vierling ever report to you that she had concerns about the Recovery filter?	A. No.
		Q. Did she ever report to you that Ms. Fuller refused to sign the cover letter of July 10, 2002, with the 510(k)	A. No.

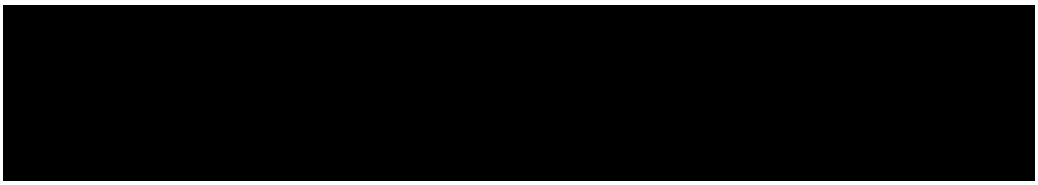
		submission for the Recovery?	
		Q. Let's look at Document 126 that's already been marked, and a previously marked document, 247. (Whereupon, Exhibit 247 and Exhibit 126, having been previously marked, were introduced.) **Exhibit 126/247 (same exhibit) BPV-17-01-00057954 - BPV-17-01 00057955**	
		Q. You were asked about these documents today, and let me see what number we put on them today, because that will make the record clearer. All right. What we talked about today as Documents 357 and 358, I'm going to ask you about those. They are in your pile if you want to pull them up.	A. Which documents are there? 357, 358. Okay, got it.
		Q. Yes. Okay	A. Got it.
		Q. And previously 357 is marked Master Exhibit 126, and 358 was previously marked 247.	A. Okay
		Q. You got those?	A. I think so.
		Q. Okay. So I want you to look first at the one we marked today, 357.	A. Okay.
		Q. And that shows, "Impra, July 10, 2002." Do you see that?	A. Yes.
		Q. Can you tell me what this item is up at the top right-hand corner?	A. That looks like a postmark from a shipping company.

		Q. In your experience at Bard, did Bard typically put a shipping label on the original letter that it would send to the FDA?	A. No.
		Q. You indicated early that -- earlier that you thought this was the library copy for Bard. Do you remember saying that?	A. Yes
		Q. Does the fact that the shipping label is on that tell you anything more about whether that is the library copy or not?	A. No.
		Q. Do you think it was the library copy? MR. LOPEZ: Objection. Calls for speculation. Lacks foundation. Also calls for an opinion.	
		Q. That's okay.	A. You are correct.
		Q. All right. Then look at the other one, which is 258.	A. 358
		Q. 358, sorry. And you have already talked about this document today, correct?	A. Yes.
		Q. And you already pointed out for us earlier today that the stamp that is on It is received by the FDA?	A. Correct
		Q. And you also pointed out that it looked like this document came from a FOI request to the FDA by reason of the fact of what the labels at the bottom say, correct?	A. That's correct.

		Q. All right. And then let's look at the second page of that, that you also have already talked about. Just so we can confirm that on that document, and let me go down, that it, again, has the FDA production number on it, correct?	A. Yes.
		Q. That that is actually signed "Carol Vierling for Kay Fuller," correct?	A. Correct.
		Q. And then the second line is "Carol Vierling"?	A. Correct
		Q. And just above the "Regards," that letter says that, "If you have any questions, please contact Kay Fuller," and it gives a fax and a phone number, correct?	A. Correct.
		Q. Did you have any information from any source that Ms. Fuller was allegedly refusing to sign that letter?	A. No.
		Q. Ms. Fuller testified that she even told Dr. Susan Alpert that she had refused to sign the letter due to concerns with the filter. Did you ever hear of such a thing? MR. LOPEZ: Well, object to the form of the question.	A. Susan never told me that there had been an allegation or a request or a statement by Kay to that effect.
		Q. Given your working relationship with Dr. Alpert, if a person working in your department had called and told her that, do you have any expectation of what information you would have received about that from	A. There would have been an investigation launched, and probably would have excluded me.

		Dr. Alpert? MR. LOPEZ: Objection. Form.	
		Q. Okay. Do you have any reason to believe that Carol Vierling forged Ms. Fuller's name on that letter?	A. No, I do not.
		Q. Did you instruct Ms. Vierling to forge Ms. Fuller's name on the letter?	A. No, I did not.
		Q. Did you instruct Ms. Vierling to sign the letter for Ms. Fuller, knowing that Ms. Fuller was refusing to sign it herself?	A. No, I did not.
	Page: Line	**Questions by Robert Boatman**	**Answers by Mary Edwards**
		Q. You were asked some questions about Carol Vierling. First, on the signature issue.	A. Yes.
		Q. Carol Vierling has testified that she did not obtain permission from Kay Fuller to sign her name. Were you aware of that?	A. I -- no, I was not.
		Q. Okay. And her rationale was, I'm allowed to sign a document unless a person expressly tells me I can't. Was that your understanding of the rule at Bard? MS. DALY: Object to the form.	A. I can't speak for Carol's thought processes.
		Q. Very well. I'm just asking you, would that have been acceptable to you, as vice president of regulatory, that a person can sign unless the other person expressly tells them	A. At this point, it did say that she's --"Carol Vierling for Kay." I would not have expected anything different. Kay certainly didn't come to me. Kay was listed as the contact person. There is nothing that would alarm me.

		that they can't sign for them?	
		MR. BOATMAN: I move to strikes as nonresponsive.	
		Q. The question is whether a person – you should sign my name as long as I don't tell you, you can't. Does that seem to you to be a reasonable rule?	A. I can only answer definitively that I would have your permission before I would sign your name.
		Q. And that's a good practice?	A. That's a good practice. There was no 10 policies or procedures in place that I recall.



Introduction:

In this analysis, I compared proportions of adverse event reports of the Recovery, G2, G2x, G2 and G2x combined, and Eclipse vena cava filters relative to their sales, to the proportions of adverse event reports for the SNF VCF. I considered six time periods, which correspond to existing BARD AE reports: 2000- Q2'03, 2000-Q3'04, 2000-Q3'05, 2000-11/2007, 2000-11/2009, 2000-7/2010. In separate analyses, I considered data from 2000-April 23, 2004, which was of special interest due to hold on the Recovery filter that was imposed in the first quarter of 2004, from 2000-February 9, 2006 and from 2000-June 30, 2006.

Data sources:

Data for this analysis are comprised of adverse event reports and monthly sales totals. The adverse event reports were extracted from the MAUDE database that is maintained by the FDA for the purpose of reporting for medical devices, as well as Trackwise (Q2'03: BPVE-01-00196343-maude2000.xls, April 23, 2004: BPVE-01-00268632, Q3'04: BPVE-01-00052935-maude.xls, Q3'05: BPVE-01-01054793.xlsx and BPV-17-01-0193291.xls, 11/2007: BPV-17-01-00188520.xls, 11/2009: BPVE-01-01501003.xls, 7/2010: BPVEFILTER-01-00050487.XLSX for BARD events and BPVEFILTER-01-00174270_2009 AERs.xls, BPVE-01-01706342_January 10 AEs.XLS, BPVEFILTER-01-00043057_July 10 2010.XLS, BPVE-01-00749928_February 10 AEs.XLS, BPVEFILTER-01-00043446_May 10 AEs.XLS, BPVEFILTER-01-00043059_March 10 AEs.XLS, BPVEFILTER-01-00043053_April 10 AEs.XLS, BPVEFILTER-01-00043058_June 10 AEs.XLS for SNF events). The sales data were provided by BARD (BPV-17-01-00193291.xlsx for sales from 2003 and BPV-17-01-00188520.XLS for sales prior to 2003).

Data inconsistencies and errors:

I note that there was an error in the calculation of migration AE's on the Recovery tab of BPV-17-01-00188520.xls: the formula in B2 should be =countif(f7:f444,b1), but actually was hard-coded as "$0.00". This changes the total Recovery migration events from 0 to 37 (cell g18 on the Rates tab, through November 2007). I also note that on the SNF tab of that same sheet, there are two migration events, rather than the one listed on the rate tab, though in a subsequent sheet that event is labeled as filter embolization. In another sheet (BPVE-01-01501003), the 11 instances of "filter tilt" were counted for G2, but the 14 instances of "tilted filter" were not counted. In the sheet that reports adverse events through July 2010 (BPVEFILTER-01-00050487 - Marauder Report by Manufacturer Summary IVC Filters 10-14-10 v5), 15 deaths due to filter embolization are listed for Recovery, and 0 for SNF, G2, G2X, Eclipse. In contrast, in the sheet that reports adverse events through November, 2009 (BPVE-01-01501003), 16 deaths due to filter embolization are listed for Recovery and 1 is listed for G2.

I have found substantial discrepancies between the company reports that I used for my analysis and internal company reports on Recovery adverse events. For example, in the data report that I used for my report through April 23, 2004 (BPVE-01-00268632), the summary table (page 2) lists 4 migration events, while the individual data list 5 migration events (page 10), the summary table does not list any filter embolization deaths, while the individual data list two deaths associated with migration, which I

take to be filter embolization deaths, and the summary table lists one tilted filter, while two are listed in the data reports (page 10). In the data reports that I used through September, 2004 (BPVE-01-00052935-maude), there are 6 migration events and 6 filter fracture events reported for the Recovery device. In a Bard memo dated September 7, 2004 (BPVE-01-01059656), there are 17 migrations and 22 filter fractures reported for Recovery. In the data reports that I used for my report through September, 2005 (BPVE-01-01054793), there are 27 migration events and 45 filter fracture events reported for the Recovery device. In a Bard report titled "Recovery Filter Adverse Events (Migrations/Fractures) (BPVE-01-00436350)," there are 55 migrations and 76 filter fractures reported. These examples indicate that the data reports that I used provided considerably lower numbers of events for Recovery than originally detected by Bard.

Adverse events:

I considered five adverse events: deaths due to filter embolization, filter fracture, migration, perforation and tilt. In some instances of the extracted data in the existing spreadsheets the AE of migration is expanded to include filter embolization and the AE of filter fracture is expanded to include detachment or detached components. I considered both the original categories, as well as these enlarged categories. In later years, filter fracture and detached components are only reported together.

Statistical methods:

Reporting Risk Ratio (RRR) to compare AE's among products:

For a given time period, for each product and adverse event (AE), I calculated the reporting AE risk as the number of AE's divided by the total sales in that time period. I then calculated the reporting risk ratio (RRR) as the ratio of the reporting risk of each product to that of SNF. The reporting risk ratio is an estimate of the measure of interest, which is the risk ratio (RR). I discuss below (under Potential Limitations) conditions under which the RRR provides an unbiased or conservative estimate of the RR. Letting x_1 denote the number of AE's for the product of interest, x_2 denote the number of AE's for SNF, n_1 denote the total units sold for the product of interest and n_2 denote the total units sold for SNF, the RRR is defined as

$$RRR=(x_1/n_1)/(x_2/n_2).$$

A value of the RRR that is larger than one reflects a higher risk for the AE for the product of interest than for SNF. An RRR that is less than one reflects a lower risk of the AE for the product of interest than for SNF. Note that if there are 0 events for SNF (i.e., $x_2=0$), the RRR will involve division by 0. I have listed these instances of the RRR as "∞" in my tables. If there are 0 events for Recovery and 0 events for SNF, the RRR involves 0's in both the numerator and the denominator. I have listed these instances of the RRR as "0/0" in my tables. For example, considering data through Q3'05, there were 79,349 SNF units sold and 33,592 Recovery units sold. There were 7 perforations observed among subjects with SNF filters and 13 perforations observed among subjects with Recovery filters. Thus, the RRR for Recovery versus SNF for this time period and for perforations is (13/33,592)/(7/79,349)=4.4. This suggests a 4.4 higher risk for perforation associated with Recovery than with SNF.

I note that the reporting risk ratio is different from the proportional reporting ratio (PRR) and the reporting odds ratio (ROR), both of which use total numbers who were implanted with the devices who report AE's as denominators and not total numbers who were implanted with the devices.

p-values for inference about RRR

To test whether an observed RRR is statistically significantly different from one (i.e., the "null" value), I calculated the p-value. The p-value is the probability that the observed RRR (e.g., 4.4) or an even more extreme RRR (e.g., a larger value than 4.4 or a smaller value than 1/4.4) could have arisen if the true RRR is actually one. If the p-value is very small (e.g., less than 0.05), we either have to believe that a highly unlikely event occurred, or that our presumption that the true RRR is equal to one is incorrect. Since the second possibility is more likely, we accept that explanation, and reject the null hypothesis that the true RRR is equal to one. That is, we conclude that the observed RRR of 4.4 is indeed significantly different from 1.

I calculated the p-values using two methods. For the first, I used approximate calculations that rely on large numbers. This approach approximates the natural log of the RRR divided by its approximate standard error as a normally distributed random variable and calculates the p-value on the basis of this approximation. The formula for the approximate standard error of the log(RRR) is given by:

$$\sqrt{\frac{1}{x1}+\frac{1}{x2}-\frac{1}{n1}-\frac{1}{n2}}$$

Where x_1 is the number of AE's for the product of interest (e.g., Recovery), x_2 is the number of AE's for SNF, n_1 is the total units sold for the product of interest and n_2 is the total units sold for SNF. Note that if there are 0 events for Recovery (i.e., $x_1=0$) or for SNF (i.e., $x_2=0$), this standard error cannot be calculated. In these instances I listed the p-value as "NA."

The second method calculates the p-value for the test of association between sales and AE's and is an "exact" test, meaning that it does not rely on any large sample approximations. I used Fisher's exact test to calculate these p-values. This approach is useful when there are zero AE's, as in many cases an exact p-value can be calculated, while it cannot for the approximate approach.

95% confidence intervals for the reporting risk ratio

I have calculated 95% confidence intervals for the reporting risk ratios for all of the analyses that include data through July 2010. The associated interpretation is that we can be 95% confident that the intervals contain the "true" reporting risk ratio. The lower bound of the interval is of greatest interest, because its distance from the value 1 is informative about the strength of the evidence in the data against a true reporting risk ratio of 1. The greater it is relative to 1, the smaller the associated p-value.

Adjustment for multiple testing

The chances of false positive findings increase with the number of statistical tests conducted. In the setting of analyses of efficacy, it is critical to account for this through some adjustment for the multiple testing, such as a Bonferroni correction. Control of the false positive rate simultaneously increases the false negative rate. Therefore, for analyses of safety, which are most concerned about controlling the false negative rate, it is more conservative not to adjust for multiple testing. The yellow highlighted cells on the summary tab identify those p-values that are less than 0.05. In sensitivity analyses I maintained an overall false positive rate of 0.05 for each AE through a Bonferroni adjustment for the p-values for each AE calculated at the six time periods. This amounts to using a p-value threshold for statistical significance of 0.05/6=0.0083. Because the analysis of the adverse events through April 23, 2004 was a pre-specified analysis of special interest due to a concurrent hold on the Recovery device, and the analyses through February 9, 2006 and June 30, 2006 were also pre-specified due to concurrent events, I did not include them in the joint analysis of the other six time periods and did not adjust the resulting p-values for multiple testing in sensitivity analysis.

Results

The reporting risk ratios and approximate and exact p-values are listed on the summary tab of the Excel workbook.

Analyses of major adverse events:

Filter Embolization Deaths:

By July 2010, there were 15 deaths associated with Recovery filters, and none associated with SNF, G2, G2X or Eclipse filters. A reporting risk ratio cannot be calculated due to the denominator of 0 from SNF, but the exact p-value can be calculated and is 8.3e-11, providing evidence of a highly significant increased risk of reports of death due to filter embolization with Recovery filters as compared to SNF filters. This highly significant result is seen starting from Q3'04 for Recovery vs SNF.

Migration:

The reporting risk ratios for migration for each filter versus SNF are over 20 by July 2010, and are as large as 288. It is striking that the lower 95% confidence bound for the reporting risk ratio for migration for Recovery versus SNF is 40.1. That means that we can be 95% confident that the true reporting risk ratio is at least 40.1. The other lower bounds for the migration risk ratios are 20.2 (G2 vs SNF), 12.9 (G2X vs SNF), 18.5 (G2/G2X vs SNF) and 1.9 (Eclipse vs SNF). In all analyses, the reporting risk ratios are all significantly greater than 1, except for G2 vs SNF (through Q3'05). Similar results are seen when filter embolization is combined with migration ("migration+"), with the exception of the Eclipse vs SNF comparison through July 2010, which has a nominally significant p-value of 0.09. I note that based on the mistaken count of 0 migration events in the original file from the company, the RRR for Recovery versus SNF is 0 and the p-value is 1, indicating that it is not significantly different from 1.

Perforation:

The reporting risk ratios for perforation are between 5 and 22 using data through July 2010 and are roughly 4-12 using the other datasets, except for the comparisons of G2X vs SNF through November 2009, G2 versus SNF through Q3'05 and Recovery versus SNF through Q2'03. These RRR's are 0 due to 0 events in G2X, G2 and Recovery in those periods, but are not significantly different from 1. The Recovery vs SNF comparison is statistically significant starting in Q3'04 (p=0.0058), with p-value decreasing to p<2.2e-16 through July 2010, and the G2 vs SNF comparison is statistically significant starting in November 2007 (p=0.00001), also decreasing to p<2.2e-16.

Filter Fracture + detached component(s) :

The reporting risk ratios for filter fracture+ are between 4 and 30 using data through July 2010 (except for the Eclipse vs SNF RRR, which is 0.47). They are between 1.5-17 for earlier comparisons, except for 0's in a few cases, as for perforation. All of the RRR's that are larger than 1 are statistically significant, and those less than 1 are not significantly different from 1. The Recovery vs SNF comparison is statistically significant starting in Q3'05 (p=4.3e-12), with decreasing p-values through July 2010 (p<2.2e-16), and the G2 vs SNF comparison is statistically significant starting in November 2009 (p=0.00005).

Tilted Filter:

The reporting risk ratios are all infinite or undefined due to there being 0 events for SNF. Statistically significant comparisons of Recovery vs SNF and of G2 vs SNF were found using data through November 2007 (p=0.0035 and p=0.000001, respectively) and through November 2009 (p=0.0005 for both comparisons). Comparisons between G2X vs SNF and G2/G2X vs SNF were also significant through November 2009. No new data were reported out to July 2010.

Analyses through specific dates:

In addition to the cumulative analyses described previously, I also considered three specific dates, which are associated with other noted events and issues in which Bard was involved.

Recovery vs SNF through April 23, 2004

The summary table (page 2) of adverse event data through April 23, 2004 (BPVE-01-00268632) does not list filter embolization deaths, filter fracture alone, or migration+filter embolization. The individual listings in subsequent pages of the document reveal some additional information and some errors in the summary table, which I have corrected to include two Recovery deaths due to filter embolization, 5 migration events, and two tilted filters. The reporting risk ratios for Recovery versus SNF for overall fatalities and for filter embolization fatalities are both infinity, the RRR is 38.01 for migration; it is 0 for caval perforation and filter fracture+, and it is infinity for tilted filter. The RRR's for fatalities overall, for filter embolization fatalities, for migration, and for tilted filter are all significantly greater than 1 (p=0.0016, 0.0135, 0.0001, 0.0135, respectively, Fisher's exact test). The other RRR's are not significantly different from 1.

G2 vs SNF through February 9, 2006

I have additionally analyzed G2 AE's versus SNF AE's through February 9, 2006. Migration events for G2 through this date are listed in BPVEFILTER-01-00008355. I used the same source for sales data as for the other analyses that I have conducted (BPV-17-01-00193291.xlsx from 2003 and from BPV-17-01-00188520.XLS for prior to 2003). I was able to infer the migration for SNF through February 9, 2006 using the Bard sheets through Q3 2005 and November 2007 because the SNF counts for migration do not change during this bracketing period. The reporting risk ratio for G2 vs SNF for migration is 135.07, which is highly significantly different from 1 (p= 2.48e-11, Fisher's exact test).

G2 vs SNF through June 30, 2006

I have additionally analyzed G2 AE's versus SNF AE's through June 30, 2006. Migration, perforation and filter fracture events for G2 through this date are listed in 2006.06.30.BPVE-01-01035539_.QUADS R002 native G2 caudal migration failure analysis.pdf (slide 7). I used the same source for sales data as for the other analyses that I have conducted (BPV-17-01-00193291.xlsx from 2003 and from BPV-17-01-00188520.XLS for prior to 2003). I was able to infer the migration and perforation counts for SNF through June 30, 2006 using the Bard sheets through Q3 2005 and November 2007 because they do not change during this bracketing period. The filter fractures increase by one during this period, and so to be conservative, I used the November 2007 count for SNF filter fractures. The reporting risk ratio for G2 vs SNF for migration is 114.9, for perforation is 14.9 and for filter fracture is 5.22. The RRR's for migration and for perforation are highly significantly different from 1 (p<2.2e-16 and p=3.6e-11, respectively).

Analyses of individual filters:

Recovery

As of **June 30, 2003**, there was a statistically significant increased reporting risk ratio for **migration** (RRR = 183, p <0.0001) for the **Recovery** compared to the SNF.

As of **February 25, 2004**, there was a statistically significant lower resistance to pressure (as determined through laboratory testing) for the **Recovery** compared to the **SNF** (see statistical analysis below)**,** which was consistent with the increased reporting risk ratio for migration events for the **Recovery** compared to the **SNF**.

As of **April 23, 2004**, there were statistically significant increased reporting risk ratios of **deaths** (RRR infinite, p =0.0016), **filter embolization death** (RRR infinite, p=0.0135), and **migration** (RRR = 38, p =0.0001) for the **Recovery** compared to the SNF.

As of **September 30, 2004**, there were statistically significant increased reporting risk ratios of **filter embolization death** (RRR = infinite, p < 0.0001), **migration** (RRR = 24, p =0.0003), **caval perforation** (RRR = 4.85, p =0.006), **filter fracture** (RRR = 12, p =0.001), and **migration plus embolization** (RRR = 33, p < 0.0001) for the **Recovery** compared to the SNF.

As of **September 30, 2005**, there were statistically significant increased reporting risk ratios of **filter embolization death** (RRR = infinite, p < 0.0001), **migration** (RRR = 63, p < 0.0001), **caval perforation**

(RRR = 4, p=0.002), **filter fracture** (RRR = 53, p < 0.0001), **migration plus embolization** (RRR = 54, p < 0.0001), and **filter fracture plus detachment of component** (RRR = 6, p < 0.0001) for the **Recovery** compared to the SNF.

As of **November 30, 2007**, there were statistically significant increased reporting risk ratios for **filter embolization death** (RRR infinite, p < 0.0001), **migration** (RRR = 114, p < 0.0001), **caval perforation** (RRR = 9, p < 0.0001), **filter fracture** (RRR = 81, p < 0.0001), **tilted filter** (RRR infinite, p < 0.0001), **migration plus embolization** (RRR = 85, p < 0.0001), and **filter fracture plus detachment of component** (RRR = 15, p < 0.0001) for the **Recovery** compared to the SNF.

As of **November 30, 2009**, there were statistically significant increased reporting risk ratios for **filter embolization death** (RRR infinite, p < 0.0001), **migration** (RRR = 135, p < 0.0001), **caval perforation** (RRR = 12, p < 0.0001), **tilted filter** (RRR infinite, p =0.0005), **migration plus embolization** (RRR = 52, p < 0.0001), and **filter fracture plus detachment of component** (RRR = 17, p < 0.0001) for the **Recovery** compared to the SNF.

As of **July 31, 2010**, there were statistically significant increased reporting risk ratios for **filter embolization death** (RRR infinite, p < 0.0001), **migration** (RRR = 288, p < 0.0001), **caval perforation** (RRR = 21, p < 0.0001), **migration plus embolization** (RRR = 109, p < 0.0001), and **filter fracture plus detachment of component** (RRR = 30, p < 0.0001) for the **Recovery** compared to the SNF. These statistically significant increased reporting risk ratios were maintained for **filter embolization death** (RRR = 11, p < 0.0001), **migration** (RRR = 48, p < 0.0001), **caval perforation** (RRR = 13, p < 0.0001), **migration plus filter embolization** (RRR = 48, p < 0.0001), and **fracture plus detachment of component** (RRR = 24, p < 0.0001) even after assuming in a sensitivity analysis that there were 5 additional adverse event reports associated with the SNF.

G2

As of **February 9, 2006**, there was a statistically significant increased reporting risk ratio for **migration** (RRR = 135, p < 0.0001) for the **G2** compared to the SNF.

As of **June 30, 2006**, there were statistically significant increased reporting risk ratios for **caval perforation** (RRR = 15, p < 0.0001 and **migration** (RRR = 114, p < 0.0001) and a marginally significant increased reporting risk ratio for filter fracture (RRR=5, p=0.0567) for the **G2** compared to the SNF.

As of **November 30, 2007**, there were statistically significant increased reporting risk ratios for **migration** (RRR = 97, p < 0.0001), **caval perforation** (RRR = 5, p < 0.0001), **tilted filter** (RRR infinite, p < 0.0001), and **migration plus embolization** (RRR = 48, p < 0.0001) for the **G2** compared to the SNF.

As of **November 30, 2009**, there were statistically significant increased reporting risk ratios for **migration** (RRR =82, p < 0.0001), **caval perforation** (RRR = 4, p < 0.0001), **tilted filter** (RRR infinite, p =0.0005), **migration plus embolization** (RRR = 20, p < 0.0001), and **filter fracture plus detachment of component** (RRR = 2.65, p < 0.0001) for the **G2** compared to the SNF.

As of **July 31, 2010**, there were statistically significant increased reporting risk ratios for **migration** (RRR =144, p < 0.0001), **caval perforation** (RRR = 19, p < 0.0001), **migration plus embolization** (RRR = 38, p < 0.0001), and **filter fracture plus detachment of component** (RRR = 6, p < 0.0001) with the **G2** compared to the SNF. These substantial and statistically significant increased reporting risk ratios were maintained for **migration** (RRR = 24, p < 0.0001), **caval perforation** (RRR = 12, p < 0.0001), **migration plus filter embolization** (RRR = 16, p < 0.0001), and **fracture plus detachment of component** (RRR = 5, p < 0.0001) even after assuming in a sensitivity analysis that there were 5 additional adverse event reports associated with the SNF.

G2x and G2/G2x combined

As of **November 30, 2009**, there were statistically significant increased reporting risk ratios for **migration** (RRR = 11, p =0.032), **tilted filter** (RRR infinite, p =0.009), and **migration plus embolization** (RRR = 4, p =0.025) for the **G2x** compared to the SNF.

As of **November 30, 2009**, there were statistically significant increased reporting risk ratios for **migration** (RRR =67, p < 0.0001), **caval perforation** (RRR = 3, p =0.0002), **tilted filter** (RRR infinite, p =0.0005), **migration plus embolization** (RRR = 17, p < 0.0001), and **filter fracture plus detachment of component** (RRR = 2.09, p =0.003) for the **G2 and G2x (combined)** compared to the SNF.

As of **July 31, 2010**, there were statistically significant increased reporting risk ratios for **migration** (RRR =94, p < 0.0001), **caval perforation** (RRR = 14, p < 0.0001), **migration plus embolization** (RRR = 26, p < 0.0001), and **filter fracture plus detachment of component** (RRR = 4, p < 0.0001) for the **G2x** compared to the SNF. These statistically significant increased reporting risk ratios were maintained for **migration** (RRR = 15, p < 0.0001), **caval perforation** (RRR = 8, p < 0.00015), **migration plus filter embolization** (RRR = 11, p < 0.0001), and **fracture plus detachment of component** (RRR = 3, p < 0.0001) even after assuming in a sensitivity analysis that there were 5 additional adverse event reports associated with the SNF.

As of **July 31, 2010**, there were statistically significant increased reporting risk ratios for **migration** (RRR =131, p < 0.0001), **caval perforation** (RRR = 18, p < 0.0001), **migration plus embolization** (RRR = 35, p < 0.0001), and **filter fracture plus detachment of component** (RRR = 5, p < 0.0001) for the **G2 and G2x (combined)** compared to the SNF.

Eclipse

As of **July 31, 2010**, there were statistically significant increased reporting risk ratios for **migration** (RRR = 20, p =0.022), and **caval perforation** (RRR = 5, p 0.017) for the **Eclipse** compared to the SNF. A marginally statistically significant increased reporting risk ratio was maintained for **caval perforation** (RRR = 4, p=0.056) even after assuming that there were 5 additional adverse event reports associated with the SNF.

Potential Limitations and responses

There are potential limitations to this analysis that need to be considered when interpreting the results:

- Underreporting: adverse events are generally considered to be underreported to the databases, and potentially differentially by severity of adverse event and by drug or medical device. If only a_1% of occurrences of a particular AE are reported for device 1 and a_2% of occurrences of that AE are reported for device 2, then the RRR will be biased for the true risk ratio, RR, as it will equal $(a_1/a_2)\times RR$. If $a_1=a_2$ then the RRR is unbiased for the RR. If $a_1<a_2$ (i.e., the extent of underreporting for device 1 is greater for device 1 than for device 2), and the true RR is greater than 1, then the RRR is a conservative estimate of the RR (i.e., it is closer to 1 than the RR). It is important to recognize that underreporting in and of itself is not problematic. Rather, differential underreporting of the higher risk device is what leads to bias. And even if there was differential underreporting of the higher risk device, given the variation in reporting relative risks across adverse events, the differential reporting would have had to have been highly variable across adverse events. This does not seem plausible given the severity of the adverse events considered. Given the magnitude of the RRR's, and their variability across adverse events, it seems implausible that differential underreporting by filter could fully explain the deviation of the observed RRR's from 1.

  The estimates of RR provide insight into the magnitude of the underreporting of SNF relative to Recovery that would be necessary to obtain the estimates that were obtained, if the true risk ratio were 1 (i.e., no difference in risk between products). For example, the RRR for Recovery versus SNF for migration events, through July 2010, is 288. This indicates that if there is truly no difference in risk of migration between Recovery and SNF, this reporting risk ratio of 288 could only arise if the probability of reporting a migration event for SNF is 288 times less than the probability of reporting a migration event for Recovery. For example, if 80% of migration events were reported for Recovery, then it would have to be the case that 0.28% of migration events were reported for SNF. Assuming that the company believed that the products were equivalent in their risks of migration, this indicates that they allowed an extremely high level of underreporting for SNF. If there was underreporting of SNF events, but of a more plausible magnitude, such as 50%, then the reporting risk ratio would have been 160 rather than 288. Many of the reporting risk ratios are around 20. Again, this suggests that if underreporting of the AE fully explains the elevated risk ratio, it would require the probability of reporting of Recovery to be 20 times that of SNF. If the company believed that there truly was no elevation in risk associated with Recovery due to SNF, but that all of the signals of elevated reporting risk were due to differential underreporting, it seems likely that they would have increased their monitoring and corrected this problem, especially if underreporting of SNF were due to decreased detection due to its permanence. The fact that this was not done, as evidenced by the *increasing* reporting risk ratios over time and the 2015 FDA warning letter (p. 1, 4, BPV-17-01-00193337), suggests that underreporting does not fully explain the reporting risk ratios.

  In summary, while the reporting risk ratios may involve some degree of underreporting, which makes them imperfect estimates of the actual risk ratios, there is strong evidence across time

periods and across AE's of similar degrees of severity to suggest that the true risk ratios are considerably larger than the null value of one.

- Overestimation of denominators: I have used sales data as a proxy for the number of patients who were implanted with the devices. In fact, not every device that was sold was actually implanted in a patient. I addressed this concern by considering in a sensitivity analysis the effect of discounting the sales numbers (through July 2010) by 20%. The reporting risk ratios for this analysis do not change from the original analysis and the p-values are all highly statistically significant ($p<1.0e-7$). If the proportion of filters implanted among those sold does not differ by filter, then this overestimation of exposure does not affect the risk ratio estimation (and would have only negligible effect on the associated p-values). And given that it does not differ by AE prevalence (without differing by filter), this could not explain the observed RRR's given their variance across AE's.

- Counting and data errors: As discussed above, there are discrepancies among company data sheets and even small errors can have large effects on small numbers of events. I addressed this concern by considering in a sensitivity analysis the effect of adding 5 to each of the adverse event totals for SNF in the data through July 2010. The reporting risk ratios are 11.1 (death due to filter embolization), 48.1 (migration), 13.4 (perforation), 48.9 (migration+), 24.5 (filter fracture+). These are all highly statistically significant ($p<1.0e-5$). Based on my analysis of the Bard AE reports, these errors were present for Recovery and not for SNF, and they all underestimated AE counts for Recovery.

- No person-time exposure/cannot calculate incidence rates and ratios: Although sales data by month are available, person-time cannot be reliably calculated because it is unknown when devices are removed or replaced. This would be necessary to calculate the incidence rate ratio, which is useful for individuals as it is a measure of instantaneous relative risk. For analyses at the population level, the risk ratio (which does not take into account exposure time) is a useful measure under some conditions. The use of sales as the denominator does not adjust for time at risk for the AE of interest. This means that estimates of risk are not comparable among products that have different overall person time at risk, unless the risk of the AE is highest close to its implantation and decreasing after that. However, because the SNF was a permanent filter, while Recovery was retrievable, it is reasonable to assume that adjusting for calendar years of sales, there would be greater person time at risk associated with SNF than with Recovery. This would mean that the RRR's present underestimates of the reporting incidence rate ratios, as they multiply them by the ratio of person time exposure of Recovery divided by SNF. Additionally, the adverse events reported for SNF are likely from some implantations that occurred prior to 2000, which are not reflected in the sales numbers that form the denominators of the reporting risk ratios. This means that the estimates for SNF are biased upward and thus the reporting risk ratios are biased downward.

- Temporal effects in reporting ("Weber effect"): Increased reporting can be observed soon after the launch of a drug, and then decrease over time. This does not appear to be the case in this

analysis, in which the RRR's mostly increase over time. Because this analysis includes approximately five years of follow-up after the removal of the Recovery device from the market, this would not be of concern for Recovery. This would be of greater concern for the newest products, such as G2X and Eclipse, which is why I have separately reported results for each product versus SNF. Furthermore, although the SNF was launched in 1990, the first death associated with it occurred in 1997 (BPVE-01-00268632, page 22).

- Reports generated by publicity ("notoriety effect" or "stimulated reporting"): This is known to occur, for example, after FDA warnings appear. It is important to look at timing of the "notoriety effect" to understand what, if any impact, the notoriety has had on reporting. Additionally, if these warnings do not differentially affect the devices, then this does not invalidate the use of the RRR as an estimate of the RR. An FDA warning letter (BPV-17-01-00193337) was sent to Bard on July 13, 2015. It was concerned with manufacturing violations of the Recovery Cone Removal System. It was additionally concerned with violations of Medical Device Reporting requirements, including not reporting to the FDA within 30 days of an event and not submitting complete patient information. While this letter might have generated stimulated reporting, since it was issued in 2015, it would not have any effect on the data used in my analysis. There were no earlier letters regarding concerns about adverse events associated with the Recovery filter, or other Bard products.

- Confounding or "channeling bias": Confounders are patient specific factors, such as age or gender or hypertension, for example, that are associated both with use of a particular device, such as Recovery, and with the AE, such as migration. If the analysis is conducted without adjustment for confounders, the RRR may be biased for the RR. However, if there are patient specific factors associated with use of a particular device, but not with the AE, or conversely, if there are patient specific factors that are associated with the AE, but not with use of a particular device, the lack of adjustment for them in the analysis does not produce bias. I am not aware of any individual level data that include potential confounding factors.

Summary

- The Recovery filter is associated with statistically significantly higher risks of the AE's of interest than the SNF filter. This is seen based on data through Q2'03 (November 2007 for tilted filter) and consistently through July 2010. The extremely small p-values convey the strong reliability of these findings. The extremely large magnitudes of the reporting risk ratios suggest that even if there was substantially increased reporting of Recovery relative to SNF (or, equivalently, substantially less underreporting of SNF), the risk ratios for the adverse events could still be considerably larger than 1. Furthermore, if the estimated risk ratios had been considered to be due to an imbalance in the reporting of adverse events, given their large magnitudes, it seems that the company likely would have carefully evaluated this through increased monitoring. This does not appear to have been done.
- The G2 and G2X filters likewise show statistically significantly higher risks of the AE's relative to SNF, over time and AE's, with the exclusion of death due to filter embolization. The RRR's for G2

for tilted filter are not significant until the data are extended through November 2007 and they are not significant for filter fracture until the data are extended through November 2009. The RRR's for G2X are significant for the data are extended through November 2009, except for caval perforation.

- While there are several issues with the available data sources that must be considered when interpreting the strong and consistent results of this analysis, they, alone, do not offer a plausible interpretation of the results that is consistent with no elevation of risk for Recovery (or other products) versus SNF. I have evaluated several of these through sensitivity analyses, which all produced results consistent with the original data.

In conclusion, the best available adverse event data for the filters considered provide compelling evidence in favor of increased risks of the adverse events that I considered. The reporting risk ratios are extremely large, which in association with their very small p-values, multiple sensitivity analyses, and consistency over time, products and AE's, suggest highly robust increased risks of adverse events for Recovery relative to SNF, and similarly, in most cases, for G2 and G2X. While these may partially reflect some differential reporting, it is implausible that they would be entirely explained by this.

Filter Migration Test Results:

Using the data listed in BPVE-01-0041 0985 from February 25, 2004, I used SAS Version 9.3, proc genmod, to fit a linear regression model for the pressure at filter migration (mmhg), adjusting for temperature (37 versus 40) and type (RF versus SF) and their interaction. The interaction term allows for the possibility that the difference in pressure between RF and SF may differ by temperature. Due to the multiple measurements taken for each sample, I used fit a linear regression model and used Generalized Estimating Equations to estimate the variance, correcting for the correlation within samples (i.e., two measurements within the same sample are expected to be more alike than two measurements from different samples). Here is the output from this model fit:

```
  The SAS System
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The GENMOD Procedure

   Exchangeable Working
       Correlation

Correlation    -0.10871333


  GEE Fit Criteria

QIC           119.6288
QICu          122.0000


                Analysis Of GEE Parameter Estimates
                 Empirical Standard Error Estimates

                          Standard   95% Confidence
Parameter        Estimate    Error       Limits            Z Pr > |Z|

Intercept         89.1300   3.9654  81.3580  96.9020   22.48   <.0001
temp      37     -12.8600   5.9440 -24.5100  -1.2100   -2.16   0.0305
temp      40       0.0000   0.0000   0.0000   0.0000     .      .
type      RF     -37.6267   4.4687 -46.3852 -28.8681   -8.42   <.0001
type      SF       0.0000   0.0000   0.0000   0.0000     .      .
type*temp RF 37    6.6052   6.7189  -6.5636  19.7740    0.98   0.3256
type*temp RF 40    0.0000   0.0000   0.0000   0.0000     .      .
type*temp SF 37    0.0000   0.0000   0.0000   0.0000     .      .
type*temp SF 40    0.0000   0.0000   0.0000   0.0000     .      .


  Score Statistics For Type 3 GEE Analysis

                          Chi-
Source            DF     Square    Pr > ChiSq

temp               1       6.06        0.0138
type               1      18.80        <.0001
```

type*temp	1	0.93	0.3358

The interaction term is not significantly different from zero (p=0.33), indicating that the difference between RF and SF does not differ by temperature. I then fit the model without the interaction term:

The SAS System
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The GENMOD Procedure

GEE Fit Criteria

QIC	118.8344
QICu	121.0000

Analysis Of GEE Parameter Estimates
Empirical Standard Error Estimates

Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Intercept		87.2276	2.9503	81.4451	93.0101	29.57	<.0001
temp	37	-9.0552	3.1668	-15.2619	-2.8484	-2.86	0.0042
temp	40	0.0000	0.0000	0.0000	0.0000	.	.
type	RF	-34.3781	2.8763	-40.0155	-28.7407	-11.95	<.0001
type	SF	0.0000	0.0000	0.0000	0.0000	.	.

Score Statistics For Type 3 GEE Analysis

Source	DF	Chi-Square	Pr > ChiSq
temp	1	6.23	0.0126
type	1	18.68	<.0001

This model fit suggests that adjusting for temperature, the pressure for RF is on average 34.4 units lower than that for SF; the p-value for this difference is <0.0001. This is consistent with the increased reporting risk for migration events for Recovery than for SNF, which is seen at all analysis times.

Digitally signed by Rebecca Betensky
DN: cn=Rebecca Betensky, o, ou, email=betensky@hsph.harvard.edu, c=US
Date: 2016.08.28 22:55:52 -04'00'

August 28, 2016

Rebecca Betensky, Ph.D. Date

Schedule 27 – Dr. Betensky's "Analysis June 2016.xls"

		Reporting Risk Ratio							Approximate p-values							Fisher's exact p-values						
		FiltEmb Deaths	Migration	Caval Perforation	Filter Fracture	Tilted Filter	migration+	filter fracture+	FiltEmb Deaths	Migration	Caval Perforation	Filter Fracture	Tilted Filter	migration+	filter fracture+	FiltEmb Deaths	Migration	Caval Perforation	Filter Fracture	Tilted Filter	migration+	filter fracture+
Jul-10	**recovery vs snf**	∞	288.39	21.72			109.99	30.08	NA	1.82E-08	8.30904E-16			2.301E-20	2.46548E-51	8.34121E-11	2.29E-51	4.85976E-24			3.3409E-74	2.57971E-94
	g2 vs snf	0/0	144.48	19.78			38.09	6.39	NA	7.18E-07	1.71904E-16			0	0	1	1.52E-42	7.475E-38			1.354E-40	1.54968E-22
	g2x vs snf	0/0	94.48	14.02			26.57	4.29	NA	7.5E-06	1.13121E-11			0	0	1	1.96E-18	5.59834E-16			9.5103E-18	1.2935E-07
	eclipse vs snf	0/0	20.72	5.18			5.18	0.47	NA	0.013325	0.007224933			0.058	0.46	1	0.021874	0.016672376			0.09149608	0.71685215
Nov-09	**recovery vs snf**	∞	135.49	12.03		∞	52.59	17.18	NA	0	0		NA	0	0	<0.000001	<0.000001	<0.000001		0.0005	<0.000001	<0.000001
	g2 vs snf	∞	82.38	4.77		∞	20.59	2.65	NA	0	0		NA	0	0	0.499	<0.00001	0.000005		0.0005	<0.000001	0.00005
	g2x vs snf	0/0	11.2	0		∞	4.67	0	NA	0.036	NA		NA	0.022	NA	1	0.032	0.217		0.0094	0.025	0.008
Nov-07	**recovery vs snf**	∞	114.91	9.76	81.78	∞	85.4	15.04	NA	0	0	0	NA	0	0	0.000003	<0.00001	<0.000001	<0.000001	0.0035	<0.000001	<0.000001
	g2 vs snf	0/0	97.15	5.65	2.74	∞	48.58	0.43	NA	0	0	0.168	NA	0	0.093	1	<0.00001	0.00001	0.164	0.000001	<0.000001	0.095
Q3'05	**recovery vs snf**	∞	63.78	4.39	53.15	∞	5.43	6.25	NA	0	0.002	0	NA	0	0	0.000000142	1.2E-13	0.002	1.1E-21	0.297	2.5E-11	4.28E-12
	g2 vs snf	0/0	0	0	0	0/0	0	0	NA	NA	NA	NA	NA	NA	NA	1	1	1	1	1	1	1
Q3'04	**recovery vs snf**	∞	24.95	4.85	12.47	0/0	33.26	1.47	NA	0.002898	0.004533154	0.001997471	NA	2.971E-06	0.417102027	0.0000531	0.00031	0.0058	0.00103	1	4.05E-10	0.428
Q2'03	**recovery vs snf**	0/0	183.31	0	0	0/0	183.31	0	NA	0	NA	NA	NA	0	NA	1	0.00002	1	1	1	0.00002	1

Notes: **cells contain symbol for infinity if there is a 0 in the denominator (indicating an extremely large reporting risk ratio)**
cells contain "0/0" if the calculation involves a 0 in the numerator and denominator
cells contain NA if the calculation cannot be done due to division by zero
cells contain blanks if there is no data available for that adverse event
migration+=migration+filter embolization
filter fracture+=filter fracture +detached component (in later years, these were not separated)
yellow highlighted cells indicate p-values that are less than 0.0083, the Bonferroni adjusted threshold for statistical signficance

sensitivity analyses for recovery vs snf:

add 5 events to SNF to each category (through july 2010)

relative risk	11.09	48.06	13.37		48.89	24.51
approximate p	3.1678E-06	6.16E-20	1.27059E-16		2.2421E-29	3.34038E-54
exact p	4.26114E-07	3.63E-45	6.42728E-21		2.1519E-68	2.8804E-90

discount total sales by 20% (through july 2010)

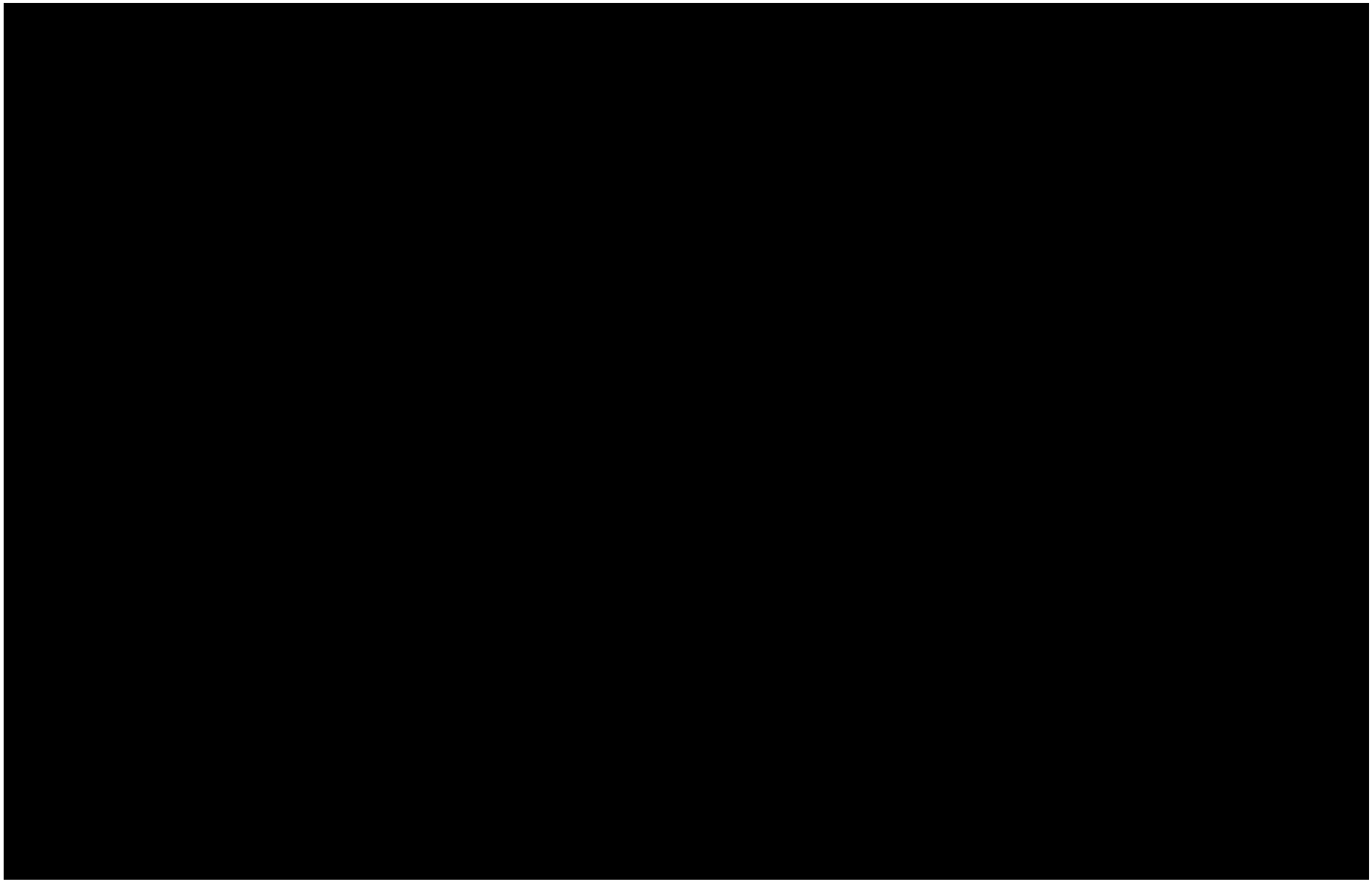
relative risk	∞	288.39	21.72		109.99	30.08
approximate p	NA	1.82E-08	8.29077E-16		2.2973E-20	2.41207E-51
exact p	8.33611E-11	2.25E-51	4.83115E-24		3.2042E-74	2.35646E-94

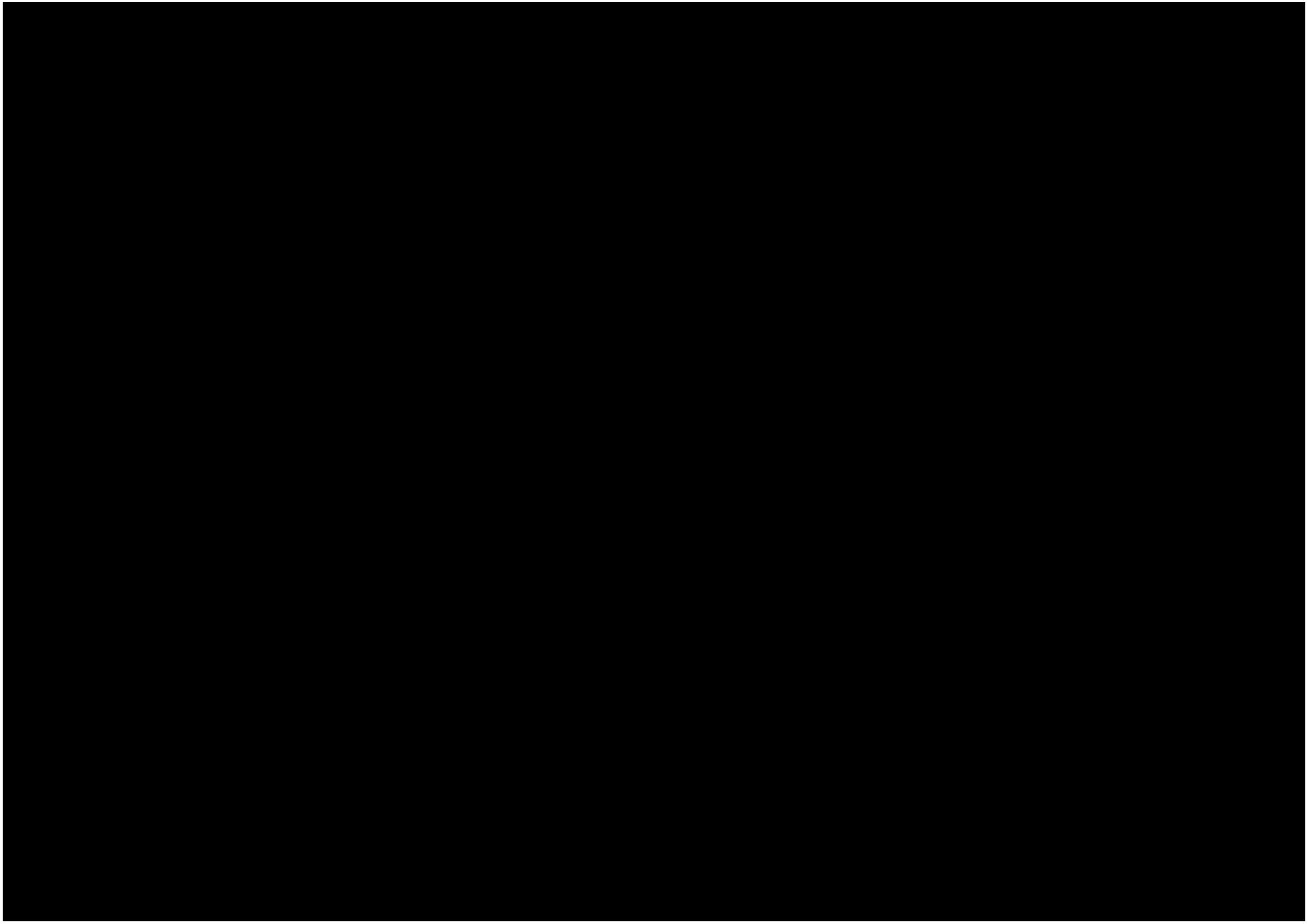
compare products from first launch to 7.5-8 years on the market (through Nov 2007 for SNF and through July 2010 for Recovery)

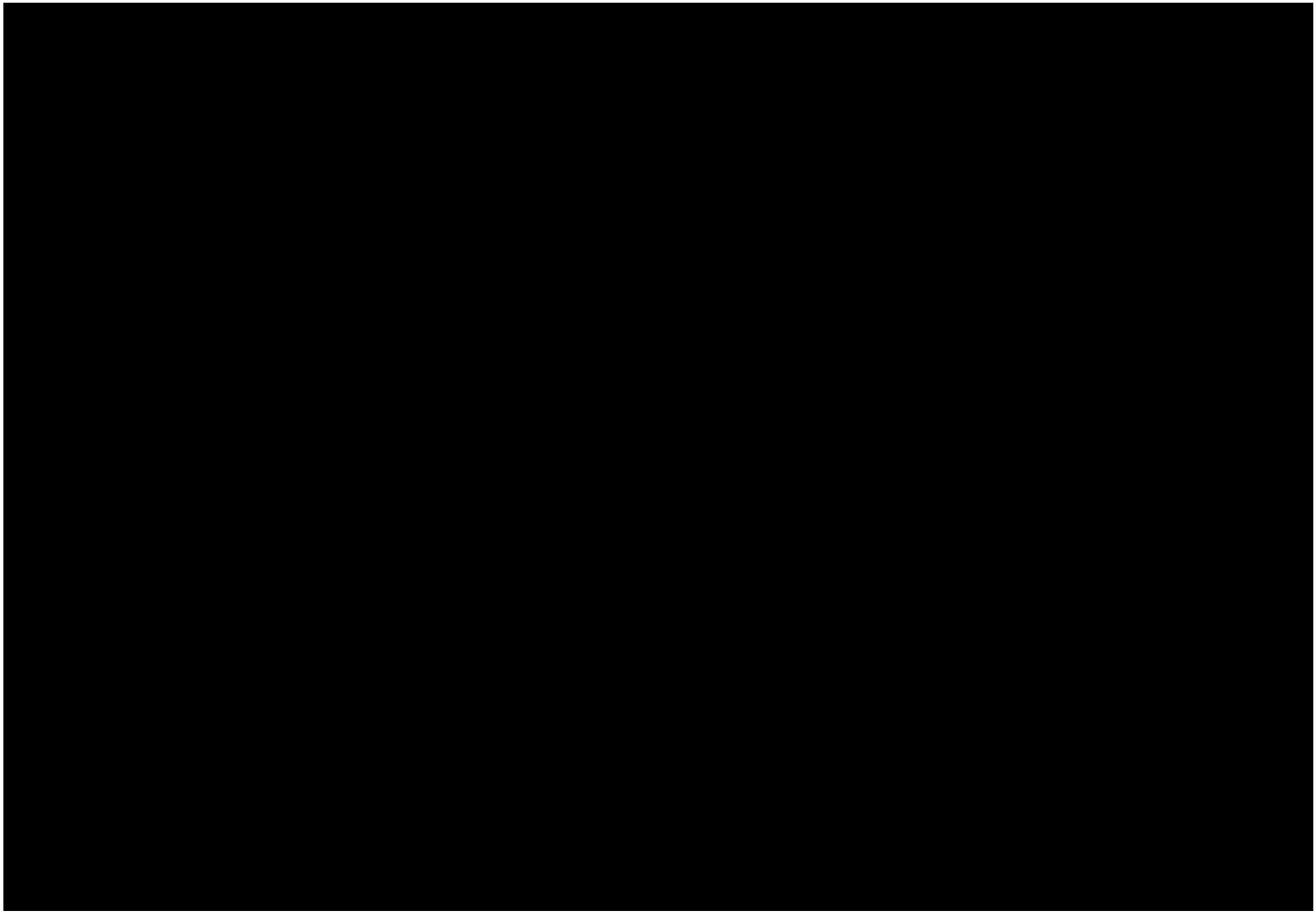
relative risk	∞	242.24	20.85		184.79	29.26
approximate p	NA	4.89E-08	6.47566E-14		2.4773E-13	1.61216E-44
exact p	8.33611E-11	2.25E-51	4.83115E-24		3.2042E-74	2.35646E-94

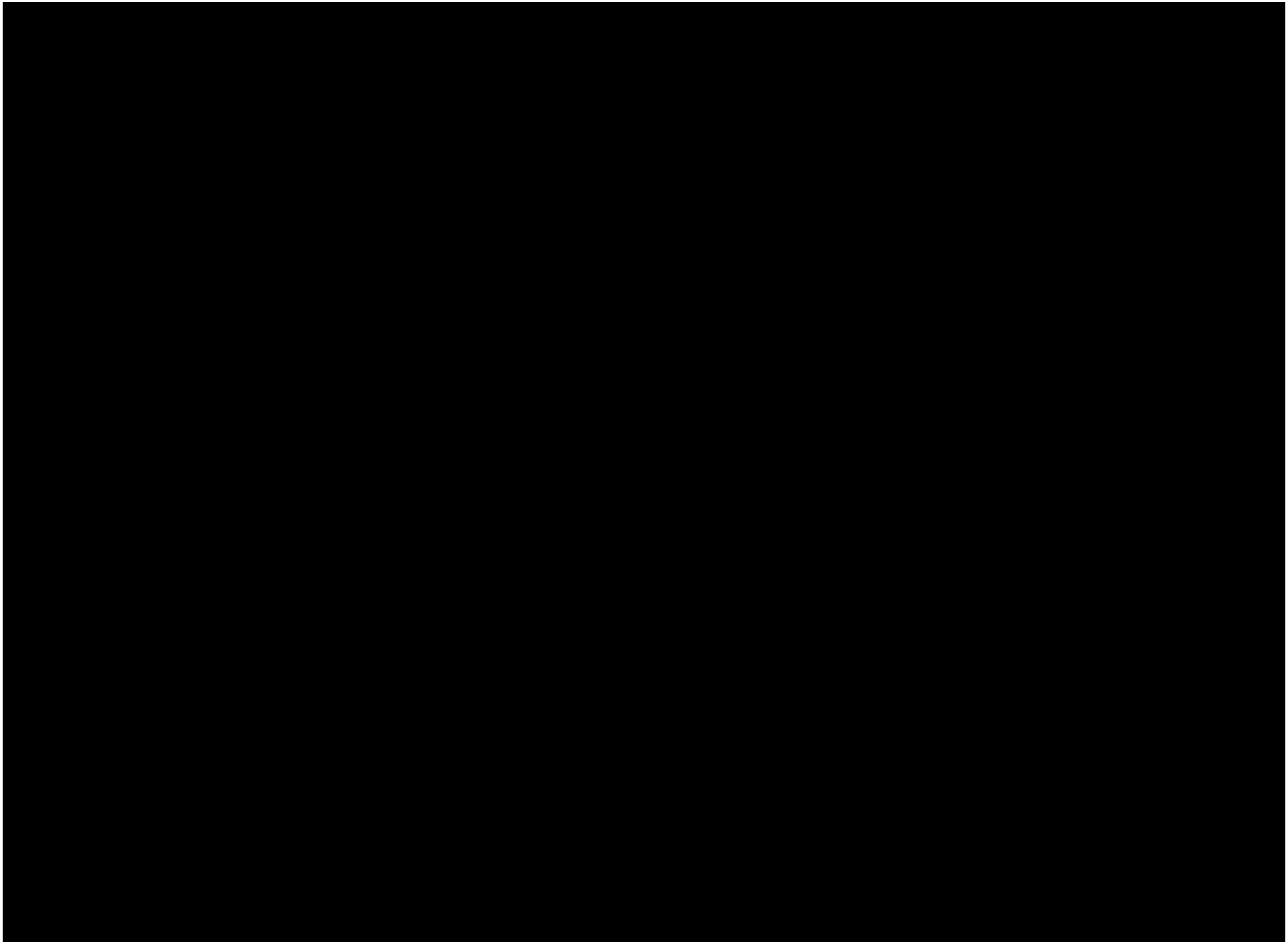
Schedule 28 – Bard's Use of Comparative MAUDE Data Among Filters

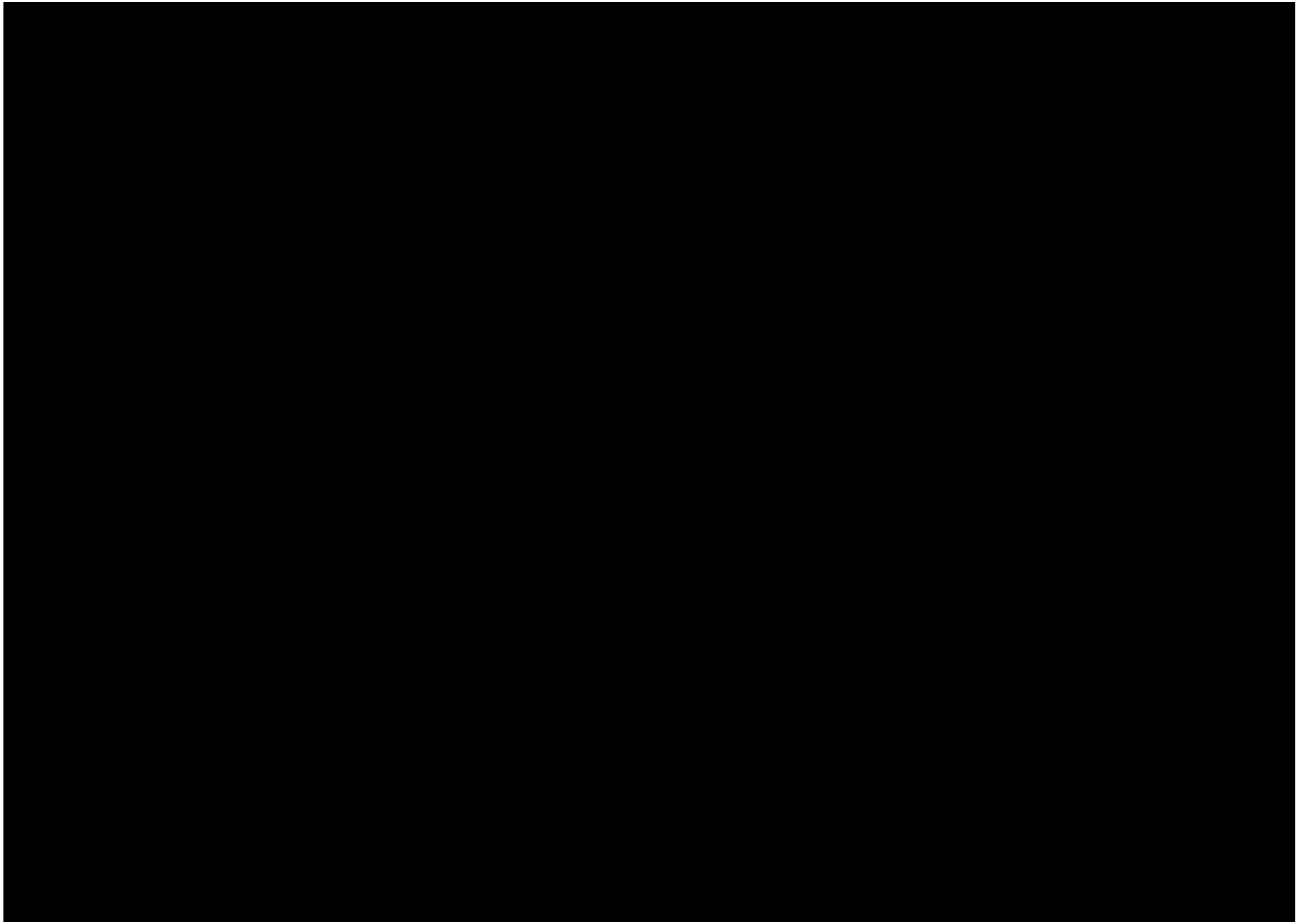
Date	Starting Bates	Author	Statement
[redacted]			

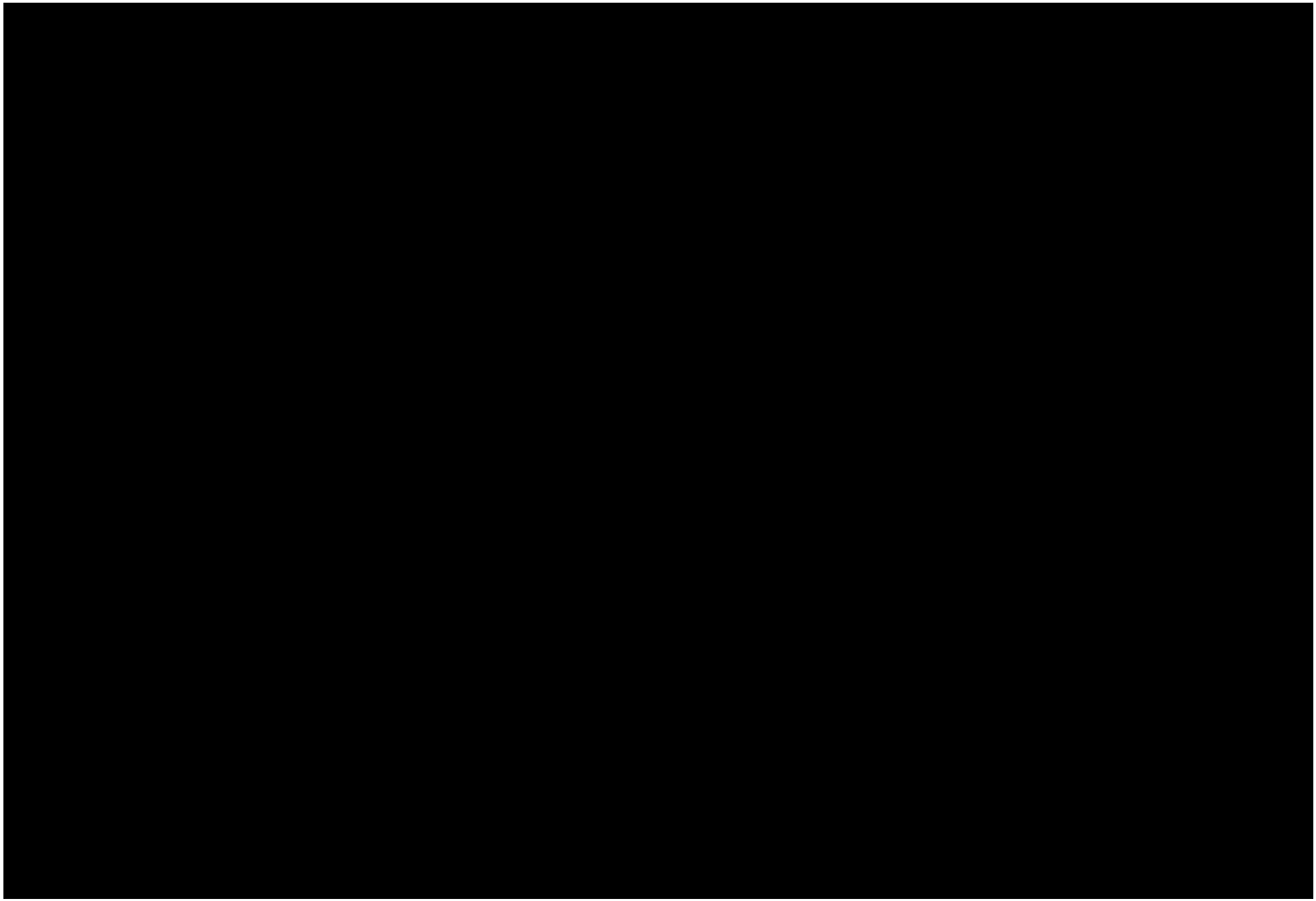


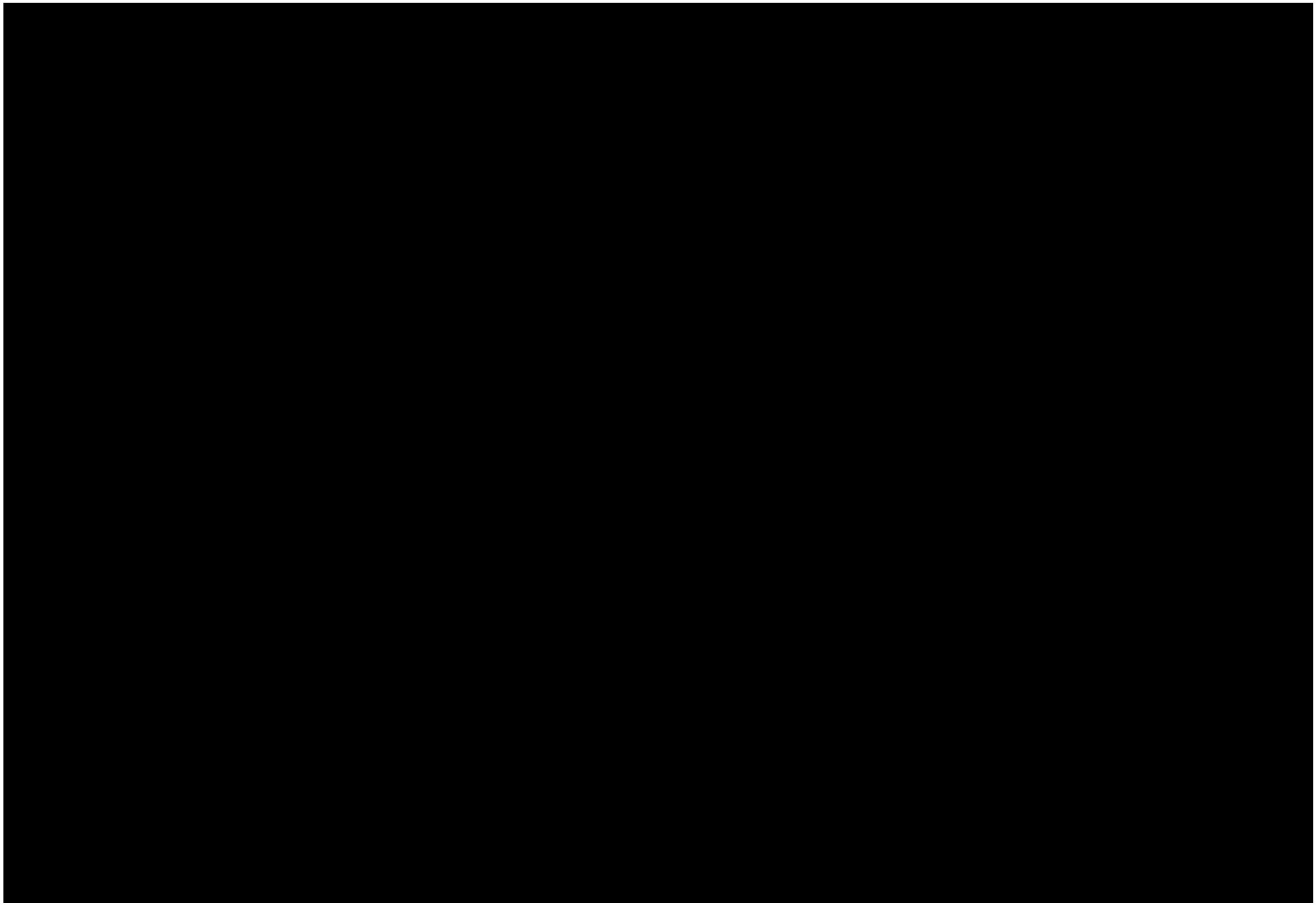


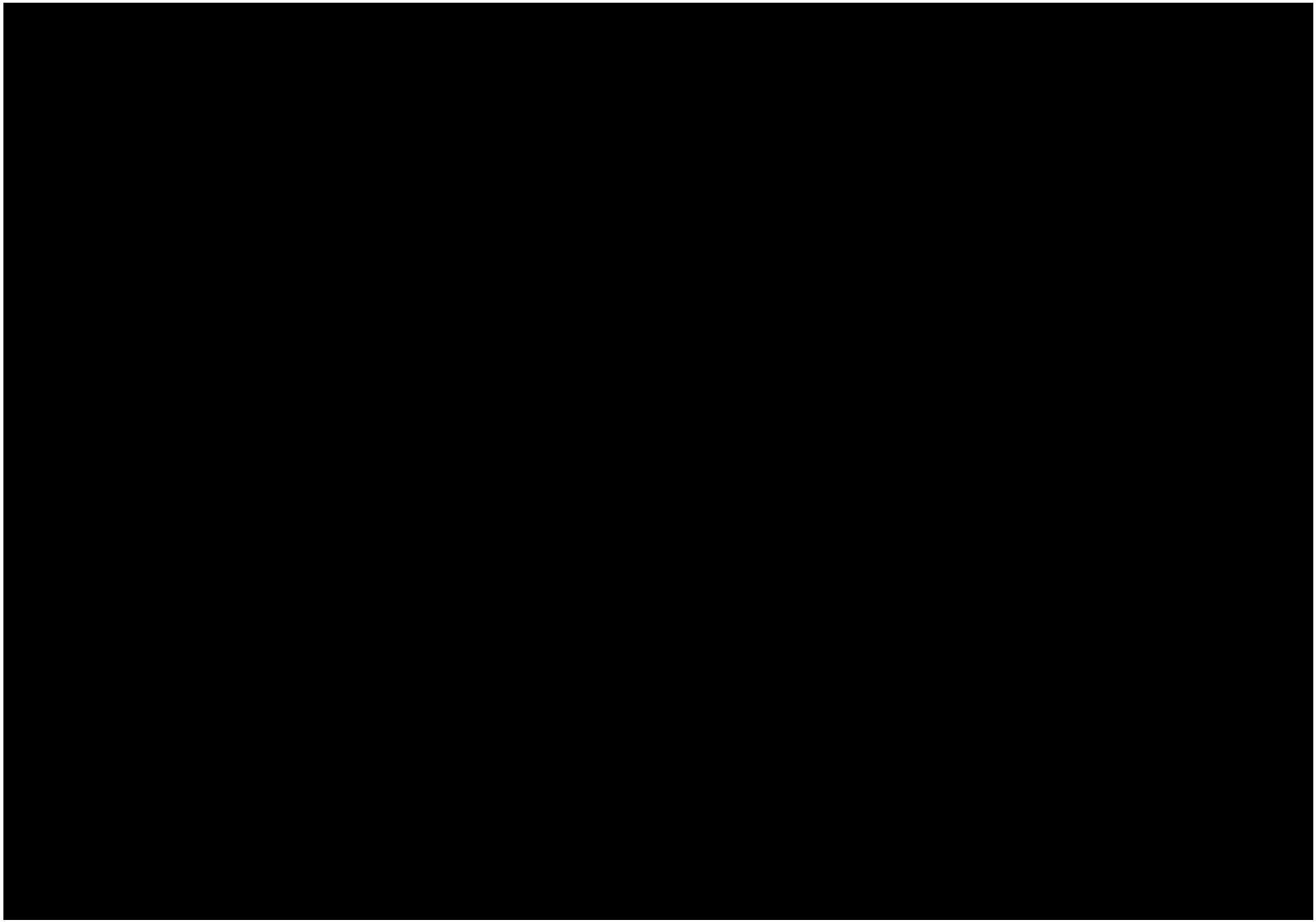


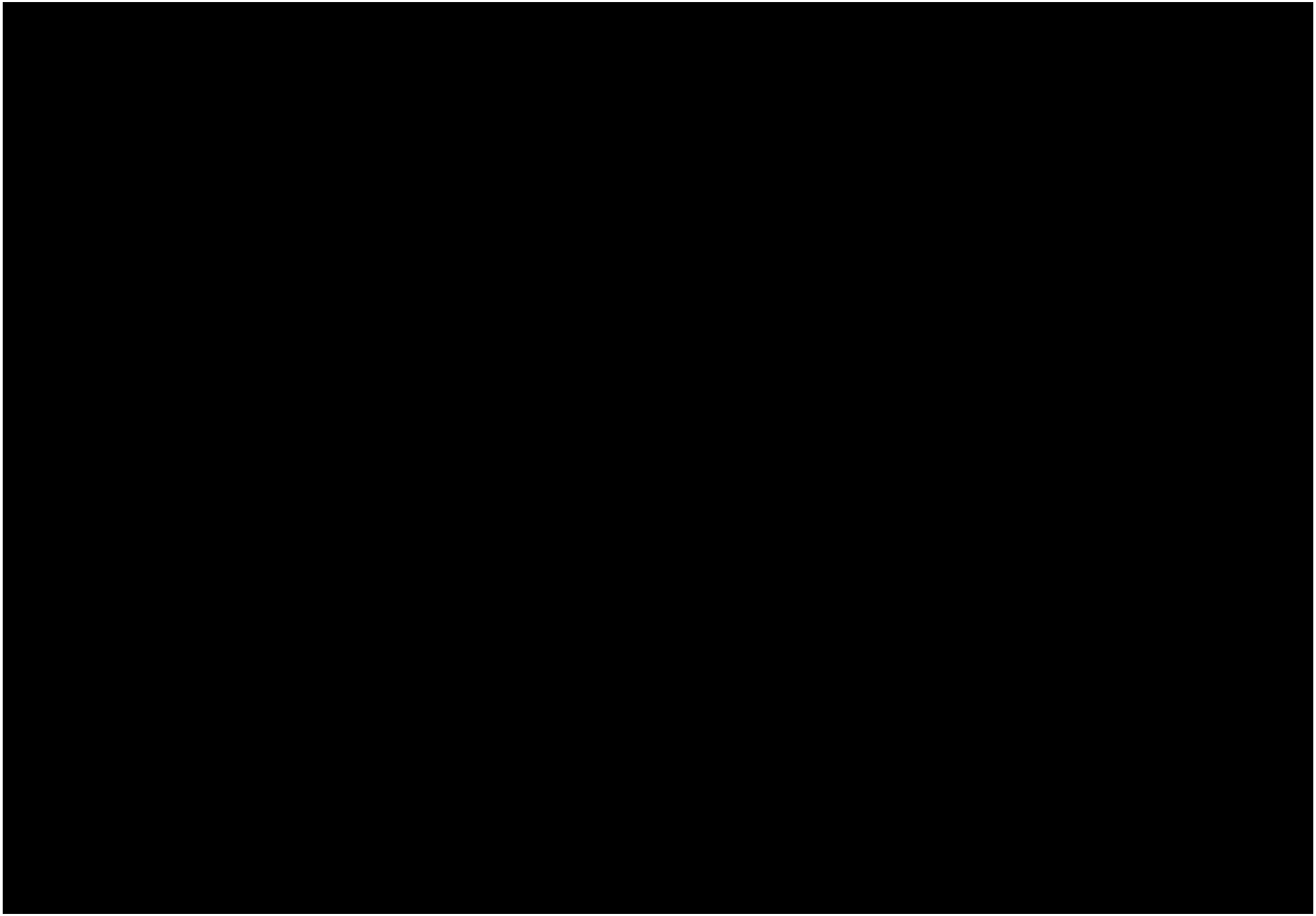


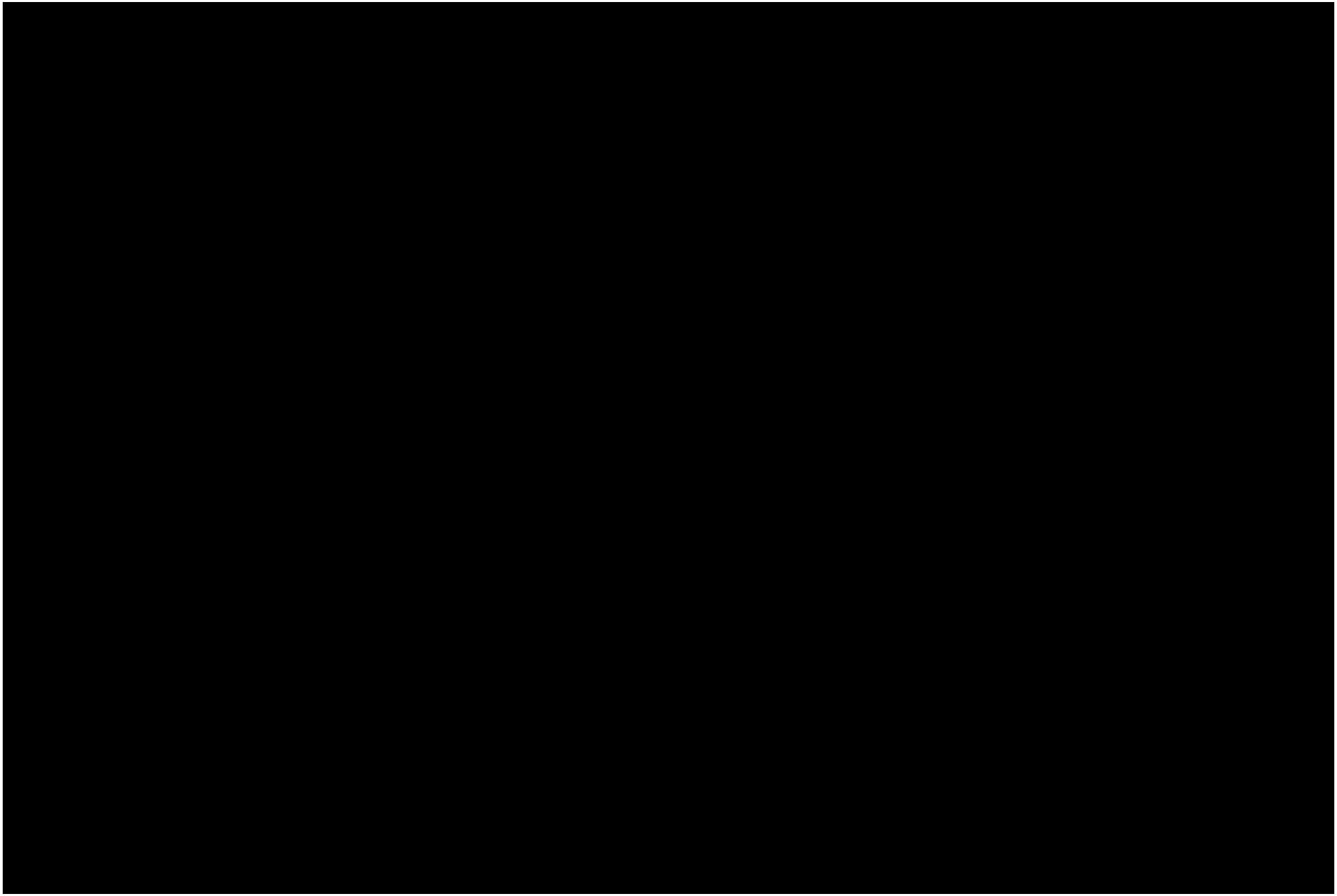


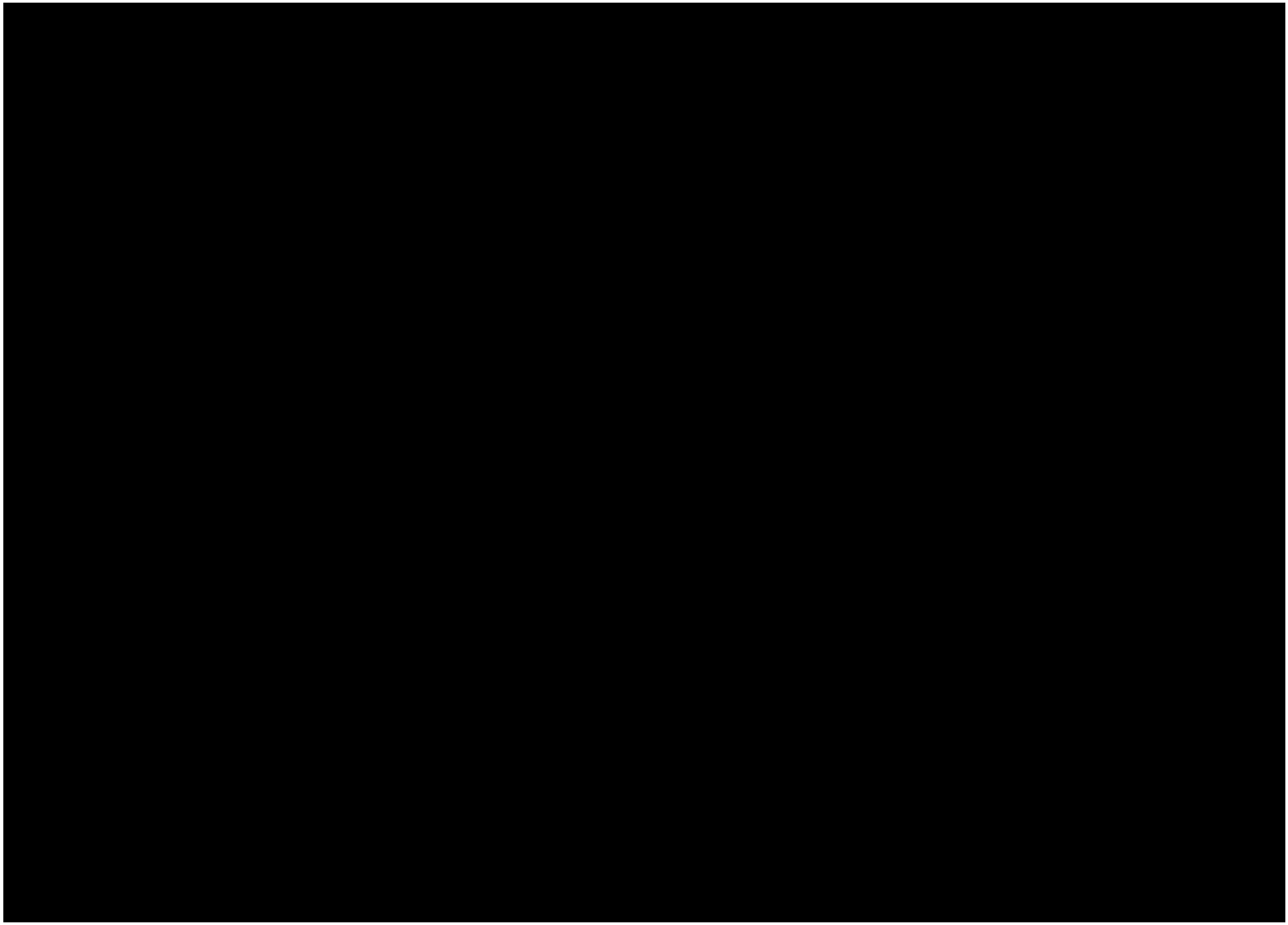


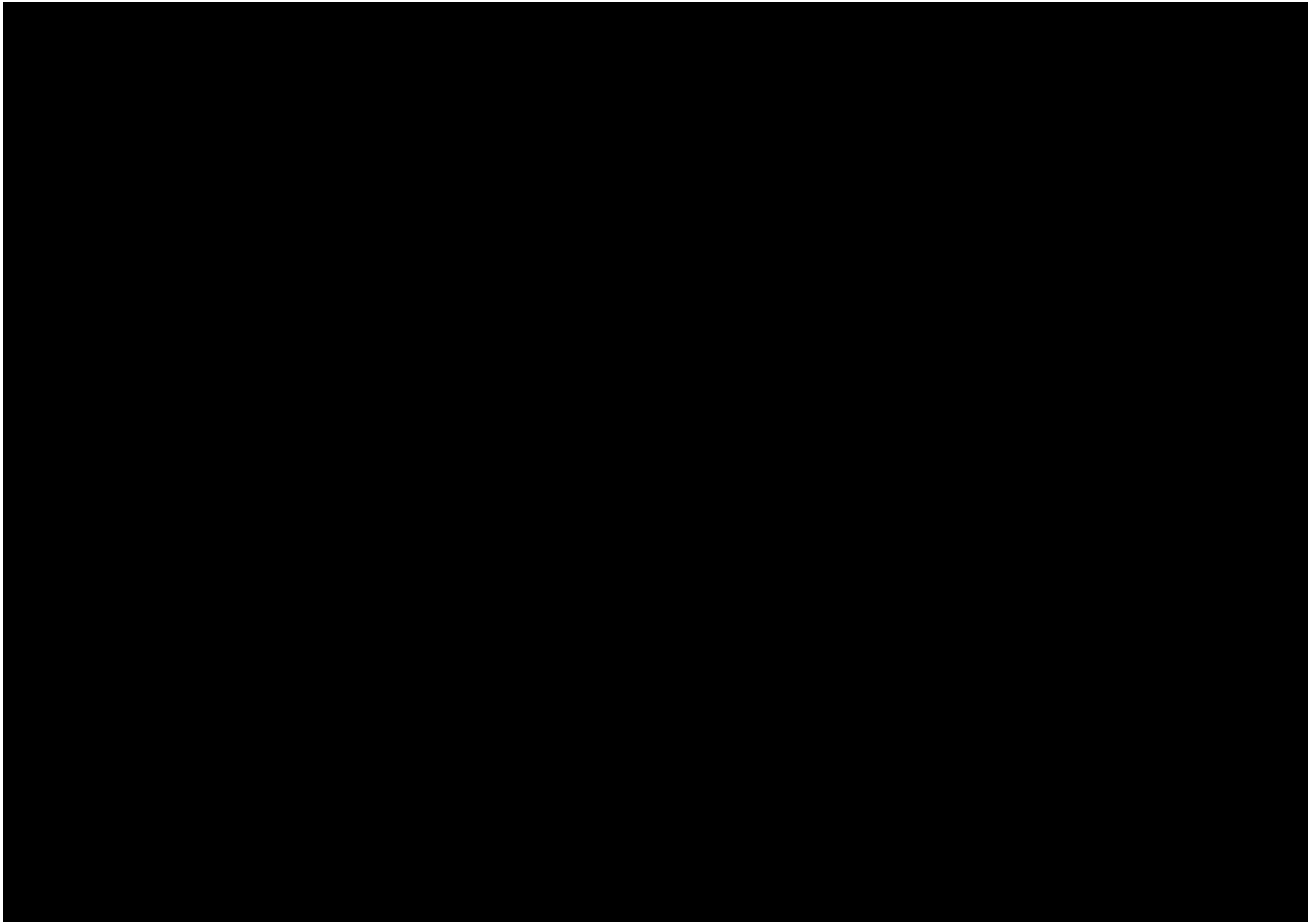


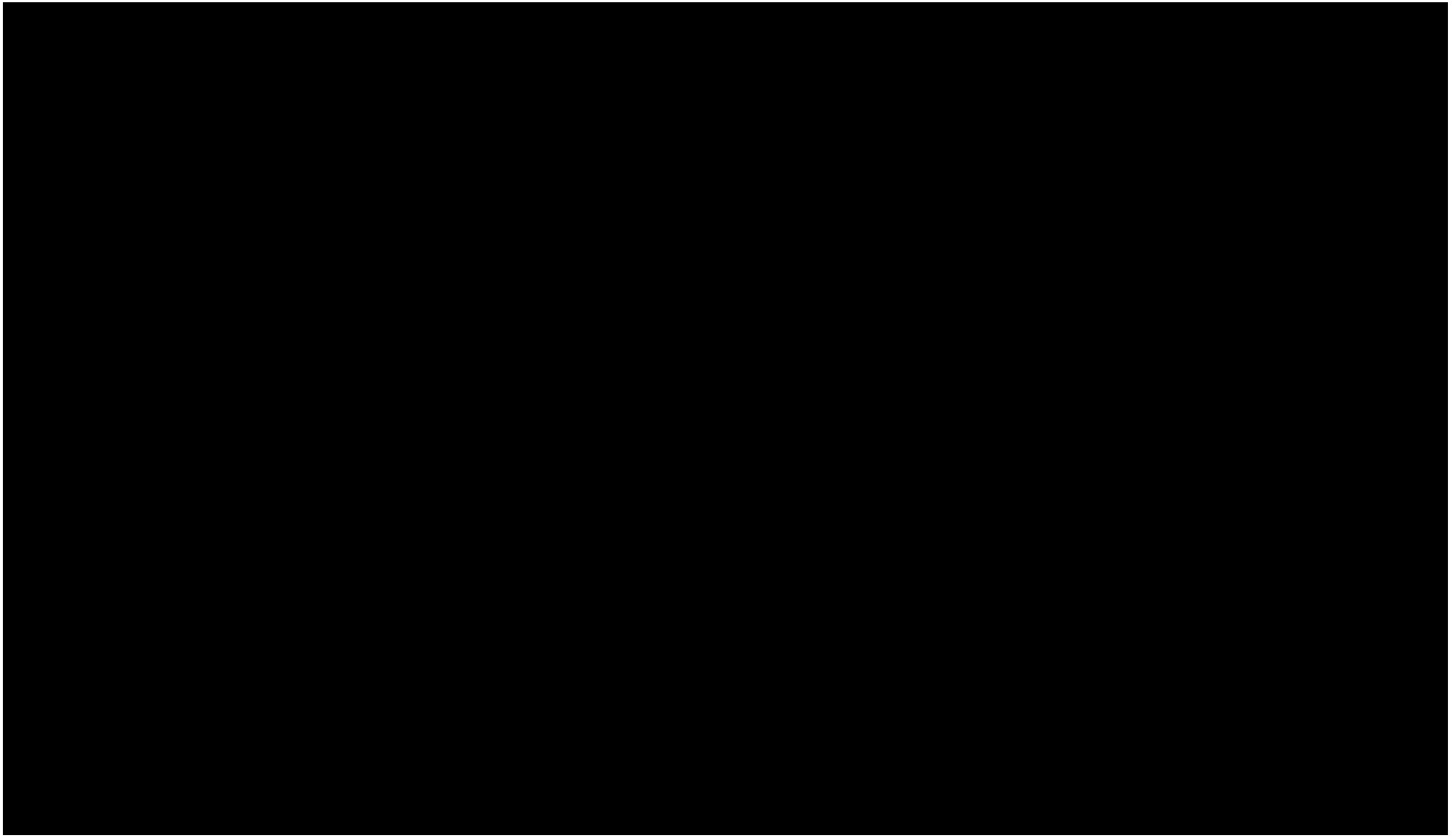


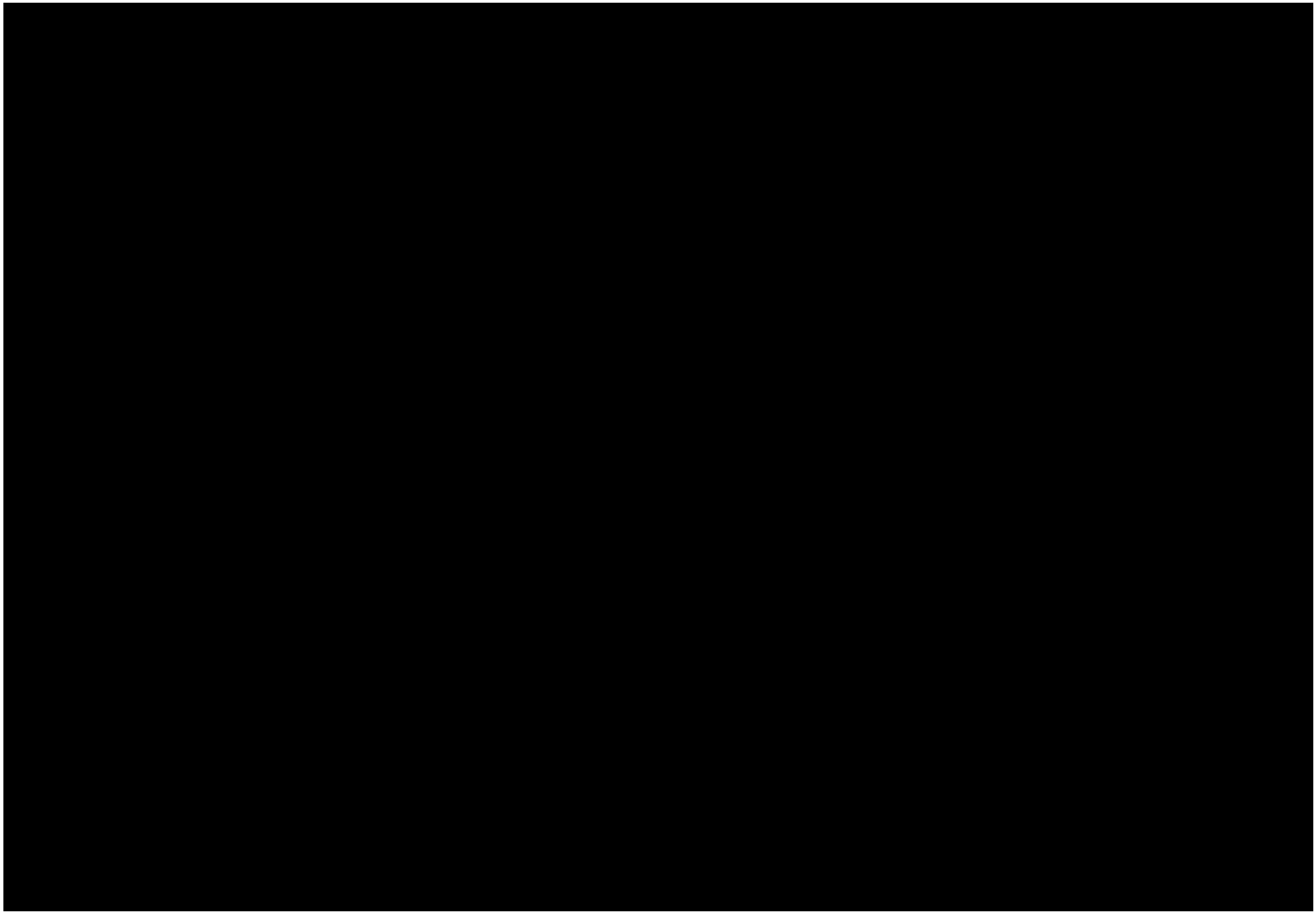


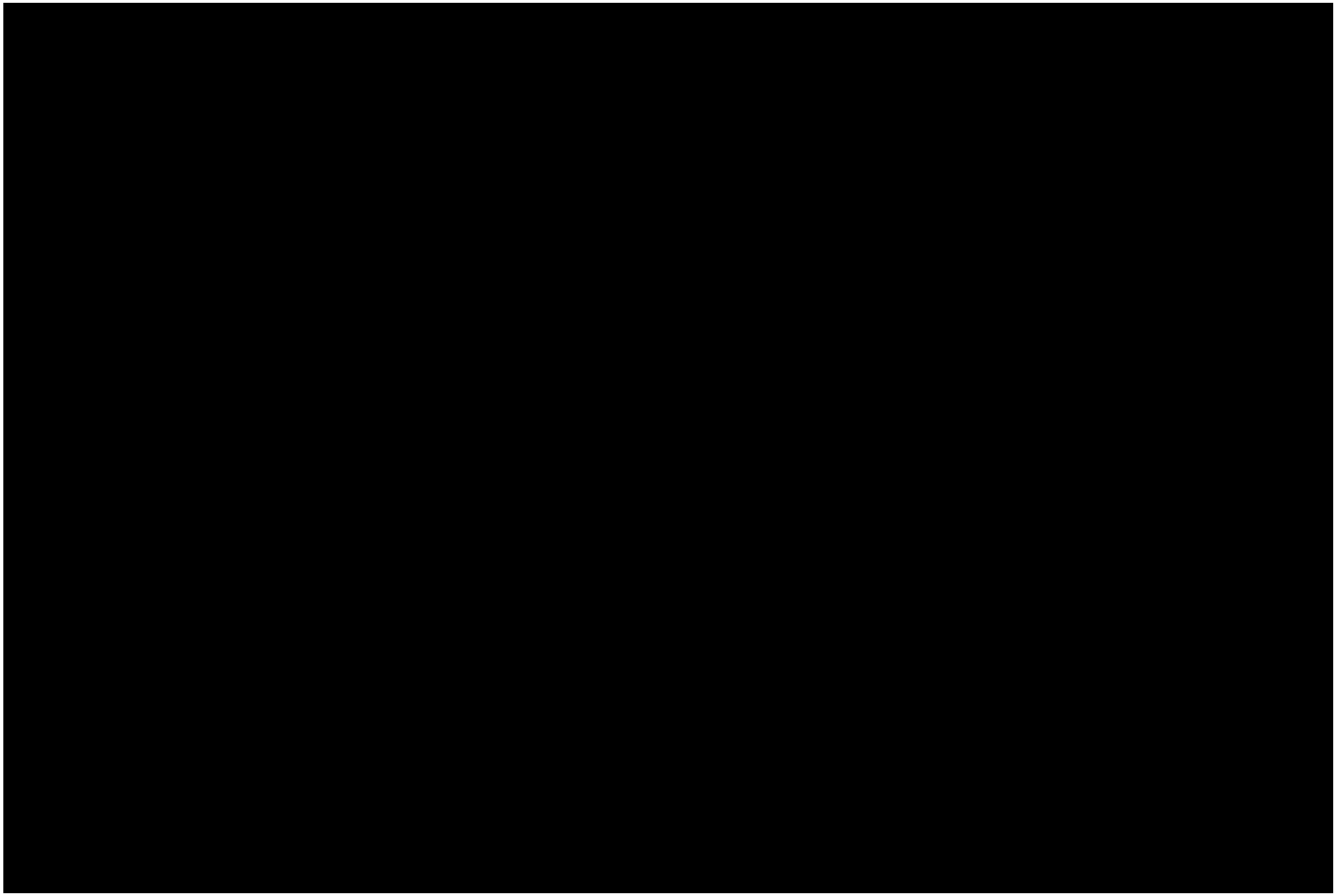


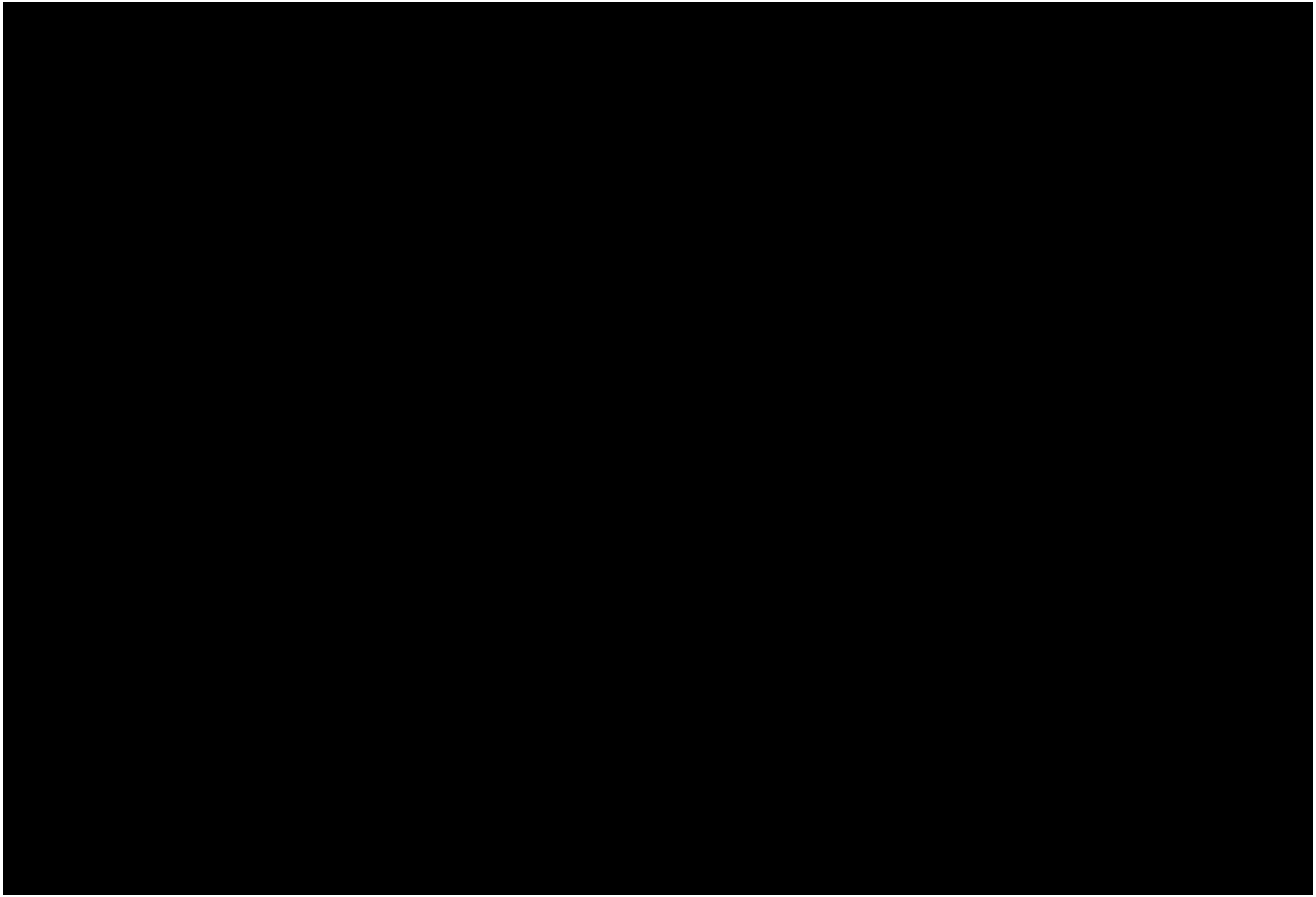












Schedule 29 - Pre-clinical testing submitted in Recovery and Modified Recovery (G2) 510(k)s

Schedule 29 - Pre-clinical testing submitted in Recovery and Modified Recovery (G2) 510(k)s

Submission Date	Device	Test/Description	Data/Results
07/10/2002	Recovery	Clot Trapping Effectiveness An in vitro model of the inferior vena cava (PVC), under strictly controlled and standardized hydrodynamic conditions comparable to those of the human body, was used to assess clot trapping ability of both the predicate (Titanium Greenfield Filter) and modified filter. This model is based on that originally described by Morris Simon, ML) (Radiology, 1993, 189: 769-774). Clots were prepared from fresh sheep blood and cut into 60rnm lengths. The series of tests was repeated 8 times in both the horizontal and vertical position for: 1 total of 80 clots delivered to one Recovery Filter and 80 clots delivered to one Greenfield Filter. *Recovery Filter 510(k)* *BPV-TRIAL-EXHIBIT-0293 0020 pg. 20*	In the horizontal position (normal use), the Greenfield Filter trapped 67% (27 of 40) and the Recovery Filter trapped 72% (29 of 40) of the clots delivered. In the vertical position (worst case), the Greenfield Filter trapped 65%'(26 of 40) and the Recovery Filter trapped 90% (36 of 40) of the clots delivered. Based on this testing, the Recovery Filter met the acceptance criteria. The Recovery Filter has a higher efficiency for clot trapping than the Titanium Greenfield Filter in both the horizontal and vertical positions.
07/10/2002	Recovery	Weld Integrity The Recovery Filter is manufactured in "bundles", with 12 wires (formed into 6 arms and 6 legs) and the sleeve (which holds the wires together). The weld joint (sleeve to wires) is a critical bond since it is the	All weld beads met the visual acceptance criteria. The average tensile strength of the weld was 14.66 lb. (min. 12.02, max. 18.94). Testing showed with 95% confidence that 99.9% of the Wire population will withstand 5 lb. of tensile force.

		only point of wire attachment to the sleeve. *Recovery Filter 510(k)* *BPV-TRIAL-EXHIBIT-0293 0023 pg. 23*	
07/10/2002	Recovery	Hook Strength The strength of the Recovery' Filter hooks was measured to determine their ability to withstand a minimum of 70 g force (equivalent to 50rnm Hg pressure in a 28mm diameter vessel acting on a filter with 6 hooks). Severity grams of force is equal to 79.5-106 g force acting on a single wire. *Recovery Filter 510(k)* *BPV-TRIAL-EXHIBIT-0293 0023 pg. 23*	All 30 samples exceeded the acceptance criteria with the lowest tensile strength of 89.8 g. Statistical analysis showed with 95% confidence that 99.9% of the samples will withstand 70 g of force prior to failure.
07/10/2002	Recovery	Corrosion/Fatigue Testing In order to pass fatigue testing, the Recovery Filter must withstand cyclic stresses comparable to 10 years of pulmonary output in a simulated environment. Sixteen filters were subjected to 36 million cycles with 1min deflection in an 18.9mm diameter tube submerged in mammalian isotonic Ringer' solution. In order to pass the test, there must be no evidence of cracks, wire deformation or any sort of physical damage to the filter under visual inspection *Recovery Filter 510(k)* *BPV-TRIAL-EXHIBIT-0293 0024 p. 24*	All filters were inspected following the testing. There were no cracks, wire deformation or any other physical damage to any of the samples. The results show that the Recovery Filter is able to withstand the stress caused by 10 years of pulmonary cycles and maintain integrity despite the corrosive environment.
07/10/2002	Recovery	Radial Strength Testing Radial strength measurements were conducted to	The results show that the Recovery Filter has a lower radial strength than the SNF, which meets the acceptance criteria of this test.

		determine the force that the Recovery Filter applies to the venous vail. Since the ideal radial strength is not known, a comparison was made to the radial strength of the SNF filter. The SNF has been marketed for more than 10 years with no known clinical complications caused by excessive radial strength. In order to pass this test, the Recovery Filter must have a radial strength equal to or less than that of the SNF. *Recovery Filter 510(k)* *BPV-TRIAL-EXHIBIT-0293 0025 pg. 25*	While these results indicate that the Recovery Filter is less likely to cause injury to the IVC wall, the migration test results provided in this submission show that the hooks of the modified filter have sufficient radial strength for proper hook engagement to the IVC wall.
07/10/2002	Recovery	<u>Simulated Use Study</u> Simulated use in an in vitro model was used to evaluate ease of deployment, filter centering, pushabilty and accuracy of placement for the Recovery Filter. Filters were deployed through a 70-degree iliac bifurcation into a 21mm Silastic tube, simulating worst case femoral delivery in an IVC. The model was submerged into a 37 degree +1-2 degrees C water bath to simulate the human environment. *Recovery Filter 510(k)* *BPV-TRIAL-EXHIBIT-0293 0027 pg. 27*	*See* attached, Schedule 29 – Appendix 1 – Simulated Use Test for Recovery Filter
07/10/2002	Recovery	<u>Spline Glue Joint Tensile Test</u> As noted previously, the spline is glued to the pusher pad using Loctite, a common adhesive. To ensure that the spline is adequately bonded to the pusher pad, tensile testing was performed. In order to pass the test, all 15 samples must withstand 3 lb. tensile force.	All 15 samples met the acceptance criteria. The minimum tensile force was 26.8 lb. with an average tensile strength of 32.1 lb.

		Recovery Filter 510(k) *BPV-TRIAL-EXHIBIT-0293 0028 pg. 28*	
07/25/2003	Recovery Filter Modification	Animal Testing Summary Using the adult sheep model, it was demonstrated that the Recovery Filter could be removed successfully both immediately after deployment and at 12 weeks. The study involved eighteen adult female Dorset or Suffolk sheep (mean weight 45±5 kg) and was in accordance with guidelines specified by the institutional animal care and use committee. The animals were divided into four experimental groups. Group A (3 animals) underwent deployment of 2 Recovery Filters each in series in the infrarenal IVC with immediate retrieval of both filters, followed by sacrifice in order to assess injury to the IVC from acute retrieval. Group B (3 animals) also had deployment of2 Recovery Filters each in series in the infrarenal IVC with immediate retrieval of both filters followed by sacrifice 3 weeks later to assess healing after acute retrieval. Group C and D (6 animals each) each had one RF filter placed in the infrarenal IVC with removal at 12 weeks. The animals in Group C were sacrificed immediately after filter removal to assess injury following retrieval at 12 weeks, while Group D were sacrificed 8 weeks after removal of Recovery Filters to assess healing after retrieval at 12 weeks.	Filter retrievals were performed by experienced Interventional Radiologists (Dr. Venbrux or Dr. Kaufman) from the right internal jugular vein approach in all cases. In Groups C&D (retrieval at 12 weeks) a 5-French pigtail catheter was first introduced into the IVC below the filter using percutaneous technique. Cavograms were performed in the anterioposterior (AP), left 45° anterior oblique (LAO) and 45° right anterior oblique projections (RAO) with Hypaque, 20ml/sec for 2 seconds through the filter removal sheath . The Recovery Filters were examined for ti1ting, migration, and thrombus formation. The IVCs were evaluated for patency. Following cavography, a 10-French retrieval sheath was advanced into the IVC above the filter. The animal then received 6,000 U heparin intravenously. The recovery cone was introduced through the sheath and opened above the filter apex. Using fluoroscopic guidance the cone was advanced to engage the apex of the filter. The filter was then removed using the technique described above. Cavograms in the AP projection were obtained from a femoral approach (through the delivery sheath in Groups A&B, through a 5-French pigtail catheter in Groups C& D) after removal of each filter. Cavograms were evaluated for evidence of extravasation, intimal irregularity

		Recovery Filter Modification 510(k) *BPV-TRIAL-EXHIBIT-0284 0019 p. 19*	or flaps, and caval patency. In Group D, hemostasis over both puncture sites was obtained using manual compression and antibiotics were given as previously described.
07/25/2003	Recovery Filter Modification	Gross and Histologic Studies All tissue samples were photographed and gross lesions identified. Tissues were embedded in paraffin, microtome sectioned to 6-micron thickness, stained with hematoxylin and eosin, or Masson's trichrome, and examined with light microscopy. The histological sections were evaluated for the presence of mural hemorrhage, disruption of the IVC and (where appropriate) the aorta, perforation and inflammation. Mural disruption or presence of inflammatory reaction were assigned a numerical score based on severity: O= none, 1 =minimal, 2=mild, 3= moderate, 4=severe or full thickness. These ratings were assigned by the pathologist based on subjective appearance. *Recovery Filter Modification 510(k)* *BPV-TRIAL-EXHIBIT-0284 0020 pg.20*	All 24 Recovery Filters were successfully removed from all 18 sheep at the scheduled times. 12 filters were removed from 6 animals immediately after placement (Groups A&B). 12 filters were removed from twelve animals at 12 weeks after placement (Groups C&D). Filter apices were easily engaged by the cone, with minimal manipulation. Filter removal was accomplished with no subjective difference in the required force between the immediate and the delayed procedures. All devices were removed intact, without mechanical failures during removal process. There were no clots or other aggregates on the devices.
07/25/2003	Recovery Filter Modification	Venacavograms	In Group A, the post-removal venacavogram was normal in all animals. In Group B, the post-removal cavogram was also normal in all animals. At 3-week follow-up cavograms the IVC was patent in all sheep, with no collateral veins seen. In Groups C & D the IVCs were patent by cavography in all twelve animals at 12 weeks.

		Recovery Filter Modification 510(k) *BPV-TRIAL-EXHIBIT-0284 0020 pg. 20*	In 4 animals there was observed to be a slight caudal migration of the filter relative to the lumbar spine (effect of parallax), and was less than 1.5 cm in all cases. An increase in filter angulation relative to the long axis of the IVC was evident in 6 animals, a decrease was observed in 4, and no change was noted in 2 animals. The mean filter angulation at 12-week-follow-up cavogram was 6°± 6°. The maximum change observed was in one Group C animal, where the angle changed from 4° to 20° , allowing the apex of the filter to appear to abut the IVC wall. Nevertheless the filter was removed without difficulty.
07/25/2003	Recovery Filter Modification	Macroscopic findings	The retroperitoneum and caval walls were intact without evidence of injury in Groups A& B. The inside of the IVC demonstrated punctate abnormalities consistent with the hooks of the filter in Group A, but was essentially normal in Group B. All Group C animals had a normal-appearing retroperitoneum. There were scattered small nodules on the adventitial surface of the IVC in the region of the filter hooks. Linear, vertically-oriented, grayish lines were visible on the adventitial surface corresponding to the arms of the filter. On the luminal surface, there were sleeves of tissue forming blind mural channels in these locations. Areas of thickening and nodularity were variably present at sites of contact by the hooks.

		Recovery Filter Modification 510(k) *BPV-TRIAL-EXHIBIT-0284 0021 pg. 21*	In Group D, all animals also had a normal-appearing retroperitoneum. These animals had fewer gross lesions than Group C animals. Adventitial nodules were also present, but on the luminal surface of the IVC; gross lesions in all animals were difficult to identify. There was nearly complete healing of the sleeves and the nodules. Solitary focal aortic adventitial nodules were present in 4 of the Group C aortas and in 5 of the Group D aortas. These corresponded to filter hooks in the adjacent IVC. In 2 Group C and 3 Group D aortas, nodules on the luminal surface of the aorta were found.
07/25/2003	Recovery Filter Modification	Microscopic findings	Punctate hemorrhages in the wall of the IVC were found in all Group A&B animals. These were consistent with the point contacts between the filter and the IVC. The hemorrhages were acute in Group A and partially resolved in Group B. There was no microscopic evidence ofhematoma, significant perivascular or dissecting hemorrhages, or endothelial necrosis. Minimal or mild intramural or transmural hemorrhage, or evidence thereof, was found in Groups C& D at points of contact with the filter. These changes were markedly diminished in Group D. No significant hemorrhage was noted on the adventitial side. Microscopic examination of the adventitial IVC nodules seen in Groups C& D showed they consisted of connective tissue.

		Recovery Filter Modification 510(k) *BPV-TRIAL-EXHIBIT-0284 0021 pg. 21*	Inflammatory cells, consisting of macrophages were also present in the neointima, within the IVC wall or on the adventitia. There was no histologic evidence to suggest infection. The inflammation score was significantly higher (p=0.002) in group C (1.4±1.0) than in group D (0.2±0.4). Mural abnormalities, evident as thinning or fibrosis within the media and adventitia, were present at points of contact in both C& D animals. The score was higher in Group C (2.9±0.9) than in Group D (2.2±0.97), but the difference was not statistically significant (p=0.07). Microscopic examination of the aortic lesions showed they consisted of fibrous tissue and were either localized on the adventitial surface or spanned a portion of the aortic wall. In 2 animals there was one site of full thickness fibrosis in the wall of the aorta adjacent to a similar lesion in the IVC. Microscopy showed neointimal proliferation over these regions within the aorta. No patent communication with the IVC lumen was present.
07/25/2003	Recovery Filter Modification	<u>Conclusion</u> *Recovery Filter Modification 510(k)* *BPV-TRIAL-EXHIBIT-0284 0022 pg. 22*	In conclusion, the Recovery Filter has been shown to be safely removed at 12 weeks after implantation using the recommended Recovery Cone.
09/19/2005	G2	The subject device filter is identical to the predicate device filter; therefore, all biocompatibility testing for the predicate filter is applicable to the subject filter. *G2 510(k)*	

		BPV-17-01-00046822	
09/19/2005	G2	Cytotoxicity Study Using the ISO Elution Method (MEM) *G2 510(k)* *BPV-17-01-00046822*	[redacted]
09/19/2005	G2	Sensitization (Murine Local Lymph Node Assay *G2 510(k)* *BPV-17-01-00046822*	
09/19/2005	G2	SO lntracutaneous Study (Irritation) *G2 510(k)* *BPV-17-01-00046822*	
09/19/2005	G2	USP and ISO Systemic Toxicity Study *G2 510(k)* *BPV-17-01-00046822*	
09/19/2005	G2	In Vitro Hemolysis Study (Modified ASTM Method) *G2 510(k)* *BPV-17-01-00046822*	
09/19/2005	G2	In Vivo Thromboresistance Study (Jugular Vein) *G2 510(k)* *BPV-17-01-00046822*	
09/19/2005	G2	Plasma Recalcification Time Coagulation Study *G2 510(k)* *BPV-17-01-00046822*	

Appendix 1 - Simulated Use Test for Recovery Filter

Simulated Use Study (continued)

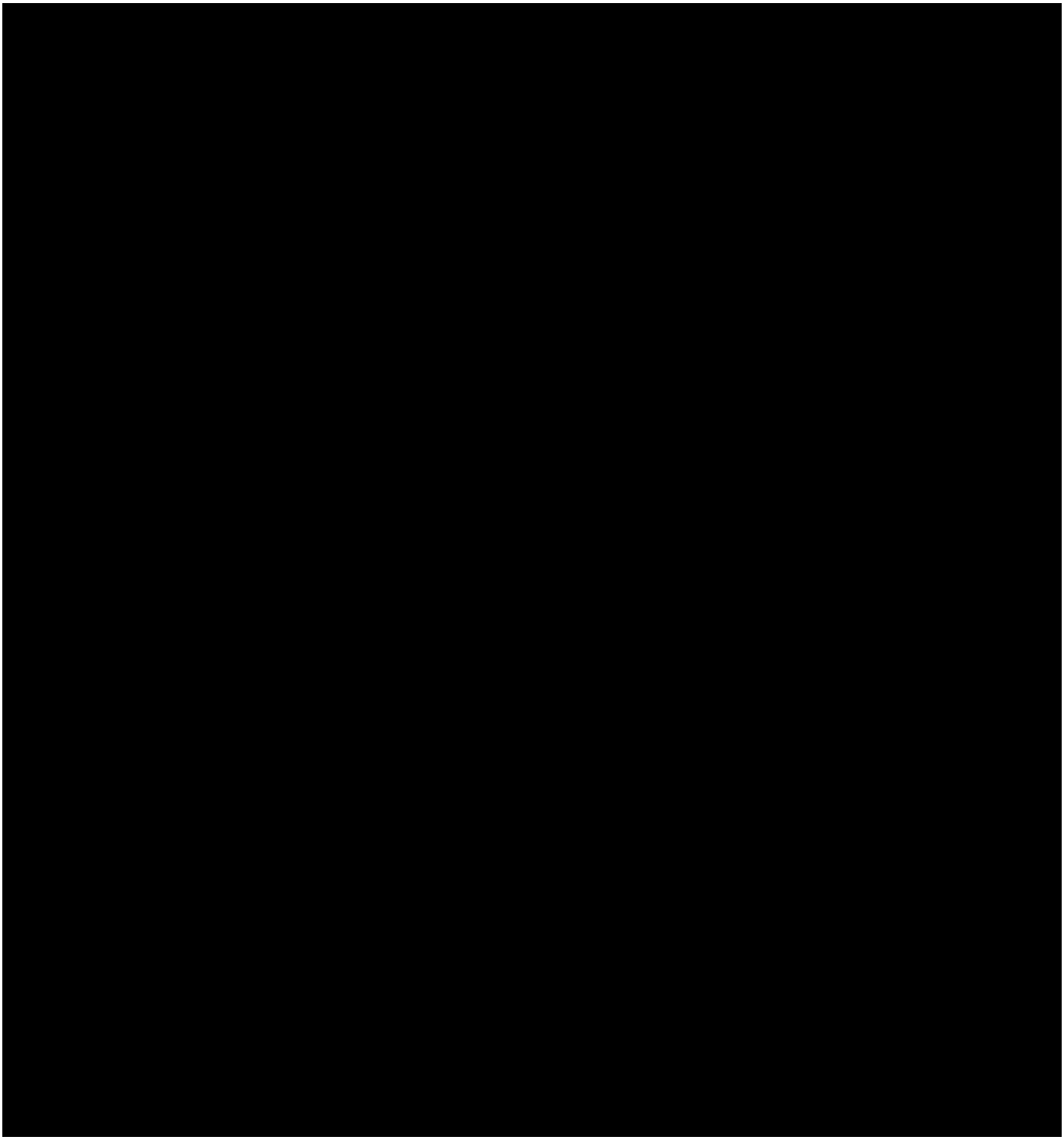


Exhibit G

Expert Report

Lisa Hyde v. CR Bard Inc.

Darren R. Hurst, M. D.
Director Vascular and Interventional Radiology
Department of Radiology
St. Elizabeth Health System
1 Medical Village Drive
Edgewood, KY 41017

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1. My name is Darren R. Hurst. I am a full time physician and fellowship trained vascular and interventional radiologist. The discipline of vascular and interventional radiology involves the diagnosis, treatment, and management of medical diseases and health conditions through imaging and targeted, image-guided, minimally invasive surgical procedures. The procedures I perform involve the introduction of medical devices into the human body under image guidance such as ultrasound, CT, and fluoroscopy. Often, this involves the use of needles, guidewires, catheters, balloons, stents, drains, and other medical devices. My education, training, and experience are detailed in my CV which is in appendix A of this report. My practice is located in Edgewood, Kentucky and serves the Greater Cincinnati, Ohio area. I am familiar with the issues, subject matter, and topics involved in this litigation. I have personal experience with the use of both permanent and retrievable inferior vena cava ("IVC") filters for the prevention of pulmonary embolism. As part of my practice, I regularly implant and retrieve IVC filters. I am familiar with the relevant medical literature that addresses the issues concerning IVC filters, including, but not limited to the indications and contraindications for use, placement, complications, and risks and benefits of the devices. I am also familiar with and have utilized multiple different types of filter devices including the Bard Simon Nitinol Filter®, Recovery Filter®, G2 Filter®, G2x Filter®, Eclipse®, and Denali Filter®. This experience, in combination with my education and training in the field of medicine, and specifically, the field of Vascular and Interventional Radiology, has formed the basis for my opinions rendered in this litigation.

2. **Case Specific Materials Reviewed**
    a. Medical Records:
        i. Wheaton Franciscan Hospital System
            1. ED records 2/24/11
            2. Interventional Radiology notes 2/25/11
            3. Consultation Pulmonary Service 2/26/11
            4. Medical Records and radiology reports 2/24/11 – 2/26/11
            5. ED visit Records 3/16/11 and 6/16/11
        ii. CT abdomen and pelvis report West Valley Imaging 6/14/13
        iii. Primary care visit notes Spark Family Medicine
            1. 5/12/14
            2. 5/16/14
            3. 5/23/14
            4. 6/14/14

iv. CT abdomen and pelvis report Steinberg Diagnostic and Medical Imaging 5/16/14

v. CXR report Steinberg Diagnostic and Medical Imaging 5/21/14

vi. Clinic visits Nevada Heart and Vascular Center

1. 6/9/14
2. 6/25/14

vii. Echocardiogram report 6/12/14

viii. Medical Records Stanford Health Care

1. IR clinic notes 8/26/14
2. IR procedure report from filter and fragment removal 8/26/14

b. Imaging Reviewed:

i. CTA chest 2/24/11

ii. Venous doppler ultrasound 2/24/11

iii. Spot films from IVC filter placement 2/25/11

iv. CTA chest 3/16/11

v. CT abdomen and pelvis 6/14/13

vi. CT abdomen and pelvis 5/16/14

vii. Chest radiographs 5/21/14

viii. CT chest 6/3/14

c. IFU

i. Bard G2 and G2x Filter

ii. Bard Recovery Filter

iii. Bard Simon Nitinol Filter

d. Bard Materials Reviewed:

i. Internal Documents: See appendix.

ii. Depositions: See appendix.

e. Medical Literature:

i. See appendix.

f. Expert Reports

i. Drs. Kinney, Roberts, and Kalva

ii. Mark Eisenberg, M. D.

iii. I have reviewed these reports, I agree with them, and I adopt the opinions and bases for those opinions set forth therein.

3. Case Summary:

a. 2/24/11 – Lisa Hyde was a 46 year old female who presented to Wheaton Franciscan Hospital with complaints of right thigh pain and swelling with mild shortness of breath on exertion for two days prior to presentation. She had a history of DVT twice in the past, most recently complicated by simultaneous pulmonary embolism. She was successfully treated as an outpatient with oral anticoagulation for 6 months. She arrived not on anticoagulants. She was found by subsequent CTA and venous-doppler ultrasound to have pulmonary embolism and recurrent right lower extremity DVT. She was presumed to be hypercoagulable given her recurrent PE and DVT and an IVC filter was recommended.

b. 2/25/11 – David Henry, M. D. brought her to the operating room for placement of a Bard G2x filter. Based on the information and records available, Dr. Henry properly placed the G2x filter consistent with the standard of care. The superior tip of filter was positioned at the superior tip of L2. The G2x filter was centered in the infrarenal inferior vena cava and the vena cava was less than 28 mm in diameter. The Bard G2x filter was indicated in the applicable instructions for use and was in accordance with the applicable standards of care. The patient was discharged without further issues.

c. 3/16/11 – Ms. Hyde presented to the ED at Wheaton Franciscan Hospital with recurrent shortness of breath and pleuritic chest pain. No significant abnormalities were discovered, and she was discharged home.

d. 5/16/14 – Ms. Hyde presented to her PCP with complaints of right lower quadrant abdominal pain and back pain intermittently for the last 1-2 years. She was sent for CT of the abdomen and pelvis.

e. 5/16/14 – CT abdomen and pelvis demonstrates a linear metallic radio-opaque foreign body in right ventricle consistent with a fractured component of her IVC filter.

f. 5/21/14 – Chest radiographs show fractured component of the IVC filter overlying the right ventricle.

g. 6/3/14 – CT Chest demonstrates the fractured component of the IVC filter in the right ventricle just below the pulmonary outflow tract.

h. 6/9/14 – Ms. Hyde presents to Nevada Heart and Vascular Center with complaints of “atypical chest pain”.

i. 6/25/14 – Ms. Hyde saw Dr. Shehane where she again complained of chest pain and the results of the echocardiogram (were discussed) confirmed the location of the strut in the right ventricle of the heart.

j. 8/25/14 – Ms. Hyde travels to Stanford Health Care for removal of her filter and filter fragment. She is seen by William Kuo, M. D. in the interventional radiology department. After clinical evaluation, she is scheduled for IVC filter removal and right ventricular foreign body removal.

k. 8/26/14 – Under general anesthesia, Ms. Hyde has a complex filter removal procedure and removal of the fractured leg from the right ventricle. She is subsequently discharged without further issues.

4. Opinions:

a. Summary:

i. Lisa Hyde was implanted with a Bard G2x® IVC filter on 2/25/11. As discussed above, the placement was consistent with the standard of care and was indicated by the applicable Bard G2x IFU.

ii. The filter subsequently caudally migrated within the inferior vena cava. This migration, and the penetration of multiple arms and legs of the filter, ultimately led to fracture of a stabilizing arm. The fractured arm embolized to the right ventricle of the heart. This caused intermittent symptoms of chest pain, pleurisy, and a fluttering feeling in the patient's chest. The fractured fragment was unstable and given its location (right ventricle) further migration would likely have caused significant morbidity or even death.

b. Reasonable Expectations of Physicians for Medical Devices:

i. In the everyday practice of medicine, I along with my colleagues/implanting and treating physicians have expectations of medical device companies like C.R. Bard, Inc. and Bard Peripheral Vascular (referred to collectively in this report as "Bard") when they design, manufacture, market, and sell medical devices. Fulfilling these expectations in their design, testing, manufacturing, warning, and marketing of IVC Filters allows physicians to properly and completely obtain informed consent from their patients. Fulfillment of these expectations also allows physicians to select the appropriate IVC filter and make appropriate therapeutic decisions on behalf of their patients whether an IVC filter is indicated or considered as a therapeutic option, and whether to use or not use a particular type of IVC filter.

ii. Moreover, a patient has reasonable expectations on what he/she should know in the same or similar circumstances as a reasonable patient who has been prescribed or has considered having an IVC filter implanted.

c. Informed Consent:

i. The AMA Code of Medical Ethics - CHAPTER 2: OPINIONS ON CONSENT, COMMUNICATION & DECISION MAKING, *2.1.1 Informed Consent* states: Informed consent to medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making. The process of informed consent occurs when communication between a patient and physician results in the patient's authorization or agreement to undergo a specific medical intervention. In seeking a patient's informed consent (or the consent of the patient's surrogate if the patient lacks decision-making capacity or declines to participate in making decisions), physicians should: (a) Assess the patient's ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision. (b) Present relevant information accurately and sensitively, in keeping with the patient's preferences for receiving medical information. The physician should include information about: (i) the diagnosis (when known); (ii) the nature and purpose of recommended interventions; (iii) the burdens, risks, and expected benefits of all options, including forgoing treatment.

https://www.ama-assn.org/sites/default/files/media-browser/code-of-medical-ethics- chapter-2.pdf.

ii. The AMA Code of Medical Ethics' Opinion 8.08 – Informed Consent states: The patient's right of self-decision can be effectively exercised only if the patient possesses enough information to enable an informed choice. The patient should make his or her own determination about treatment. The physician's obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient's care and to make recommendations for management in accordance with good medical practice. The physician has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice. Informed consent is a basic policy in both ethics and law that physicians must honor, unless the patient is unconscious or otherwise incapable of consenting and harm from failure to treat is imminent. In special circumstances, it may be appropriate to postpone disclosure of information (see Opinion 8.122, "Withholding Information from Patients").

Physicians should sensitively and respectfully disclose all relevant medical information to patients. The quantity and specificity of this information should be tailored to meet the preferences and needs of individual patients. Physicians

need not communicate all information at one time, but should assess the amount of information that patients are capable of receiving at a given time and present the remainder when appropriate.

http://journalofethics.ama-assn.org/2012/07/coet1-1207.html.

I have adopted the above AMA Codes in my daily practice and, in my opinion, they represent the standard of care relative to Informed Consent, Patient Communication, and Decision Making.

d. Failure to Notify:

i. Given the above responsibilities of the medical device manufacturer to the patient and the physician, and the physician to the patient, it is my opinion that Bard failed to notify the operating physicians and the implanted patients of the much higher complication rates associated with the Recovery®, G2x®, and Eclipse® filters in comparison to the original predicate device, the Simon Nitinol Filter®, and competitor filters. Instead, Bard continued to represent its filters as having superior safety, quality and performance. (Example: G2 Brochure: "…strength and stability to a new level.")

ii. There were multiple early safety signals with the Recovery®, G2x®, and Eclipse® filters. These signals came from adverse event reports/sales data, from reports in the medical literature, from Bard's internal risk analysis, and from Bard's own in vitro testing indicating low migration resistance compared to other filters, and in some instances, failing to meet the minimum arbitrary threshold for migration resistance under a variety of foreseeable circumstances. For example, Bard's own internal risk analysis deemed the G2 filter to pose an "unacceptable risk" of caudal migration.

iii. Despite the above warning signs that the predicate device to Ms. Hyde's filter, the Recovery filter, had significant issues with safety, Bard continued to market the device for both permanent and retrievable indications in the prevention of PE from DVT. During this time, Bard acknowledged design flaws that needed to be corrected, but instead chose to inappropriately utilize the data from the Grassi paper, and ignore their in-house studies, risk analysis, and the current medical literature, to justify the high complication rates and continued marketing practices. In essence, Bard chose to keep the product on the market until a new product was released rather than focusing on its duty to remove unsafe devices from the market.

iv. In addition, Bard marketing materials falsely represented newer generation devices as greatly improved strength and stability when many of the changes in the devices from generation to generation were minimal and unproven in their safety and efficacy.

v. Bard elected to not perform studies to further evaluate the safety, effectiveness, and durability of their filters. Instead, they embarked on a long-term plan to evolve their filter through multiple generations while making small incremental changes to each generation in response to the safety issues that were arising in real time in patients that were unknowingly participating in a decade long open experiment with Bard retrievable filters.

vi. At the time Ms. Hyde was implanted with her filter, Bard's next generation filter, the Meridian, was the first Bard filter to add caudal anchors for the purpose of "improving caudal migration resistance and tilt performance." As Bard was aware, the Eclipse filter was identical to the G2 and G2X filters with exception of electropolishing. Each of these filters suffered from a significant increased safety risk of caudal migration (a risk which Bard internally deemed "unacceptable") over competitor filters, and even earlier Bard filters (including the Simon Nitinol); Bard was aware of this information at the time Ms. Hyde was implanted with her filter. Bard was also aware at that time that caudal migration leads to tilt, perforation/penetration, complicated or high risk retrievals and fracture. Bard initiated an internal project to correct caudal migration of the G2 filter beginning in February of 2006, a fact that was not passed on to physicians or patients, and making no changes to address those caudal migration problems until launch of the Meridian in August of 2011. Moreover, despite awareness of the need to correct the caudal migration problem with its filters, Bard launched the G2X and Eclipse, filters to which no changes were made to address the caudal migration safety risk, prior to launching the Meridian. Despite all of this, Bard continued selling the G2/G2X filter at the time it was implanted in Ms. Hyde, and did not remove that filter from medical facilities. In my opinion, Bard should have never launched the G2/G2X filter without the safety design changes required by the unacceptable risk of caudal migration the company knew existed with the G2 by late 2005/early 2006 and/or should have recalled/removed that filter from the market. Ms. Hyde ultimately suffered from all of the G2/G2X filter complications the Meridian attempted to correct, including caudal migration, fracture, perforation and tilt of the filter.

vii. Had I been Ms. Hyde's implanting physician, and aware of the safety issues that were known to Bard at the time of implantation of this device, I would not have used Bard filters for the prevention of PE in my patients. No reasonably prudent physician would have. I would have also advised my partners and colleagues to do the same. It is my opinion that Bard did not adequately warn physicians, including Ms. Hyde's implanting physician, of important safety risks and issues associated with its filters of which it was aware. Moreover, the information disseminated by Bard was false and misleading about such risks, design, performance, effectiveness and utility.

e. Failure of the Bard G2x® Filter in Lisa Hyde:

i. Lisa Hyde needed protection from the sequelae of possible DVT and PE. Thus, she needed a caval filtration device that could safely and effectively provide protection**.** Bard represented the G2x® IVC filter as a device that took "strength and stability to a new level" and could be safely placed temporarily or permanently, provide effective protection from PE, and then be easily removed percutaneously without any time limitation. Given this backdrop, I render the following opinions:

1. At the time of implantation, the risks associated with this G2x filter exceeded the alleged benefits to Ms. Hyde who needed safe and effective protection against DVT and PE.
2. Lisa Hyde's G2x filter has failed to perform as a reasonable physician and/or patient would expect in that it perforated her vena cava, interacted with and perforated surrounding vital organs and structures, and a piece of the filter fractured and migrated to the heart, necessitating a complex removal procedure at a tertiary care medical center with its attendant risks of additional morbidity and mortality.
3. Because the filter could not be removed using the standard techniques and equipment recommended by Bard, she had a complex filter removal procedure at a tertiary care medical center more than 500 miles from her home. This removal required advanced percutaneous techniques with associated risks that included, without limitation, IVC perforation, bleeding, filter fracture, filter migration, IVC thrombosis, IVC stenosis, infection, and morbidity and mortality.

f. Basis of Opinions:

i. My opinions are based on the reasonable expectations I have and other similarly situated physicians have in regards to the responsibilities of a medical device manufacturer in regards to the design**,** marketing, sales, and performance of their medical devices.

ii. My opinions are based on my review of scientific and medical literature, the materials and medical records/films in this case, Bard internal documents, depositions, expert reports, and my clinical experience, education, and training. I did my own medical literature research and review, as well as reviewing literature provided to me by the plaintiff's counsel.

iii. In rendering my opinions in this matter, I took into consideration Ms. Hyde's co-morbidities, medical history, and preexisting problems.

iv. All of my opinions are to a reasonable degree of medical and scientific certainty.

v. I understand that discovery is ongoing in this case. There may be additional information in the form of medical literature, expert reports, depositions, and case material. I reserve the right to amend my opinions if further pertinent information is discovered/obtained.

Darren R. Hurst, M.D. 6/2/2017

APPENDIX

Bard Materials and Depositions Reviewed:

1. Janet Hudnall Email to David Rauch dated 2/26/04
2. Health Hazard Evaluation from David Ciavarella dated 12/17/04
3. G2 Perforations from Christopher Ganser dated 11/10/05
4. G2 Caudal Migrations from David Ciavarella dated 12/27/05
5. G2 Filter System - indicated for retrieval
6. G2 Filter System - Patient Questions & Answers
7. SWOT - Objective: Increase Revenue and Capture More Market Share
8. Monthly Global PV Report from John McDermott dated 2/10/06
9. Health Hazard Evaluation from David Ciavarella dated 2/15/06
10. G2 Caudal Migration Update dated 3/2/06
11. G2 Fracture Report November 2008
12. G2 and G2X Fracture Analysis dated 11/30/08
13. BARD IVC Filter Program May 2009 – Mike Randall
14. Letter from Stacy Taiber to Brent Adamson, M.D.
15. Filter Naming Memo from Bill Little dated 4/27/10
16. Eclipse 510(k) sections on changes to filter from predicate
17. Eclipse Product Performance Specification for Migration from Design History File
18. Meridian Product Performance Specification for Caudal Migration from Design History File
19. Meridian Value Proposition from Design History File

20. Meridian Commercialization Plan dated 10/1/10
21. G2 Platinum PowerPoint
22. Scott Karch Email to Dr. Thomas dated 3/6/12
23. Brian Barry Deposition - 1/31/14
24. Robert Michael Carr, Jr. Deposition - 4/17/13
25. Robert Michael Carr, Jr. Deposition - 10/29/14
26. Robert Michael Carr, Jr. Deposition - 11/5/13
27. Clement J. Grassi, M.D. Deposition - 7/30/14
28. Clement J. Grassi, M.D. Deposition - 8/27/14
29. Clement J. Grassi, M.D. Deposition - 9/24/14
30. Murray Asch, M.D. Deposition – 5/2/16
31. Kay Fuller Deposition – 1/11/16
32. David Ciavarella, M.D. Deposition – 11/12/13
33. Christopher Ganser Deposition – 10/11/16
34. Janet Hudnall Deposition – 11/1/13
35. John McDermott Deposition – 2/5/14
36. Gin Shultz Deposition – 1/30/14
37. Douglas Uelmen Deposition – 10/4/14
38. Carol Vierling Deposition – 5/11/16
39. Natalie Wong Deposition – 10/18/16
40. Steven Williamson Deposition – 9/7/16
41. Medical Monitoring 30(b)(6) Deposition (John Van Vleet) – 1/17/17

Literature Reviewed:

MEDICAL ARTICLES	
TITLE	AUTHOR(S)
Technical Success and Safety of Retrieval of the G2 Filter in a Prospective, Multicenter Study	Binkert
In Vitro Metal Fatigue Testing of Inferior Vena Cava Filters	Bjarnason
Comparison of the Recovery and G2 Filter as Retrievable Inferior Vena Cava Filters	Cantwell
Quality Improvement Guidelines for the Performance of Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism	Caplin
Complications Encountered with the Use of the Greenfield Filter	Carabasi
Prophylactic and Therapeutic Inferior Vena Cava Filters to Prevent Pulmonary Emboli in Trauma Patients	Carlin
Update on Vena Cava Filters	Carman
G2 Inferior Vena Cava Filter: Retrievability and Safety	Charles
Prophylactic Inferior Vena Cava Filters: Do They Make a Difference in Trauma Patients? (abstract only)	Cherry
Complications of vena cava filters: A comprehensive clinical review	Cipolla
TrapEase Inferior Vena Cava Filter Placed via the Basilic Arm Vein: A New Antecubital Access	Davison
Removal of Fractured Inferior Cava Filters: Feasibility and Outcomes	Dinglasan
Celect Inferior Vena Cava Wall Strut Perforation Begets Additional Strut Perforation	Dowell
Perforation of the IVC: Rule Rather Than Exception After Longer Indwelling Times for the Gunther Tulip and Celect Retrievable Filters	Durack
"Reporting the Impact of Inferior Vena Cava Perforation By Filters"	Wood

JOURNAL OF VASCULAR SURGERY; Vol. 55, No. 1	
PRESERVE Study to be a Comprehensive Evaluation of Inferior Vena Cava Filter use	Endovascular Today
Clinical Experience with the Antecubital Simon Nitinol IVC Filter	Engmann
Inferior Vena Cava (IVC) Filters: Initial Communication: Risk of Adverse Events with Long Term Use	FDA
Percutaneous Inferior Vena Caval Filters: Follow up of Seven Designs in 320 Patients	Ferris
Medical Literature and Vena Cava Filters	Girard
Quality Improvement Guidelines for Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism	Grassi
Vena Caval Occlusion after Simon Nitinol Filter Placement: Identification with MR Imaging in Patients with Malignancy	Grassi
Long-Term Follow-up of the Antheor Inferior Vena Cava Filter	Harries
Retrieval of the Recovery Filters after Arm Perforation, Fracture, and Migration to the Right Ventricle	Hull
Bard Recovery Filter: Evaluation and Management of Vena Cava Limb Perforation, Fracture, and Migration	Hull
Single Institution Prospective Evaluation of the Over-the-Wire Greenfield Vena Caval Filter	Johnson
Vena Cava Filter Fracture: Unplanned Obsolescence	Johnson
Decision Analysis of retrievable inferior vena cava filters in patients without pulmonary embolism	Morales
Recovery Vena Cava Filter: Experience in 96 Patients	Kalva
Practice Patterns and Outcomes of Retrievable Vena Cava Filters in Trauma Patients: an AAST Multicenter Study	Karmy-Jones
Guidelines for the Use of Optional (Retrievable and Convertible) Vena Cava Filters	Kaufman
Guidelines for the Use of Retrievable and Convertible Vena Cava Filters:	Kaufman

Report from the Society of Interventional Radiology Multidisciplinary Consensus Conference	
Development of a Research Agenda for Inferior Vena Cava Filters: Proceedings from a Multidisciplinary Research Consensus Panel	Kaufman
Update on Inferior Vena Cava Filters	Kinney
High Risk Retrieval of Adherent IVC Filters: Techniques and Management of Thrombotic Complications	Kuo
High-Risk Retrieval of Adherent and Chronically Implanted IVC Filters: Techniques for Removal and Management of Thrombotic Complications	Kuo
Modified Loop Snare Technique for the Removal of Bard Recovery, G2, G2 Express, and Eclipse Inferior Vena Cava Filters	Lynch
Removal of the G2 filter: differences between implantation times greater and less than 180 days	Lynch
Complications of the Nitinol Vena Caval Filter	McCowan
Indications for Vena Cava Filters for Recurrent DVT	Miller
Reporting Standards for Inferior Vena Caval Filter Placement and Patient Follow-up: Supplement for Temporary and Retrievable/Optional Filters	Millward
Improving Inferior Vena Cava Filter Retrieval Rates: Impact of a Dedicated Inferior Vena Cava Filter Clinic	Minocha
Realistic expectations and candidate selection for entry level vascular technologist in a busy laboratory	Mutyala
Letter to the Editor: A Complication of a G2 Bard Filter	Nazzal
Complications Related to Inferior Vena Cava Filters: A Single-Center Experience	Nazzal
Long-term Follow-up of the Bird's Nest IVC Filter	Nicholson
Prevalence of Fracture and Fragment Embolization of Bard Retrievable Vena Cava Filters and Clinical Implications Including Cardiac Perforation and Tamponade	Nicholson
Refrain, Recover, Replace	Nicholson

Correction to Article About Prevalence of Fracture and Fragment Embolization of Bard Retrievable Vena Cava Filters	Nicholson
Removal of Retrievable Inferior Vena Cava Filters with Computed Tomography Findings Indicating Tenting or Penetration of the Inferior Vena Cava Wall	Oh
Recovery G2 Inferior Vena Cava Filter: Technical Success and Safety of Retrieval	Oliva
Recovery G2 vena cava filter retrievability study	Oliva
Intracardiac Migration of Inferior Vena Cava Filters	Owens
Long-term Results of the Simon Nitinol Inferior Vena Cava Filter	Poletti
Aortic Pseudoaneurysm after Penetration by a Simon Nitinol Inferior Vena Cava Filter	Putterman
Complications of Inferior Vena Cava Filters	Ray
Outcomes with Retrievable Inferior Vena Cava Filters: A Multicenter Study	Ray
Medical Devices and the FDA Approval Process	Redberg
Simon Nitinol Inferior Vena Cava Filter: Initial Clinical Experience	Simon
Vena Caval Filters	Smith
Is Market Growth of Vena Cava Filters Justified?	Smous
Embedded Inferior Vena Cava Filter Removal: Use of Endobronchial Forceps	Stavropoulos
Complications of Vascular Access Procedures in Patients with Vena Cava Filters	Streib
Fracture and Distant Migration of the Card Recovery® Filter: A retrospective Review of 363 Implantations for Potentially Life-Threatening Complications	Tam
Vena Tech Vena Cava Filter: Experience and Early Follow-Up	Taylor
Management if Severe Vena Cava Filter Tilting: Experience with Bard G-2 Filters	Turba
FDA Safety Communication: Removing Retrievable Inferior Vena Cava	U.S. Food and

Filters	Drug Administration
Fractured Bard Recovery, G2, and G2 Express Inferior Vena Cava Filters: Incidence, Clinical Consequences, and Outcomes of Removal Attempts	Vijay
Retrievability and Device-Related Complications of the G2® Filter: A Retrospective Study of 139 Filter Retrievals	Zhu

CV:

Darren R. Hurst, M. D.

Personal Information:

- Address: 3325 Stettinius
  Cincinnati, OH 45208
  Phone: 513.403.7018
  E-mail: dhurst@cinci.rr.com

Education:

- Fellowship in Vascular and Interventional Radiology
  University of Michigan Medical Center
  1999-2000

- Residency in Diagnostic Radiology
  University of Michigan Medical Center
  Dept. Award for Research Excellence 1999
  1995-1999

- Doctor of Medicine
  University of Cincinnati College of Medicine
  AOA Honor Society 1994-95
  1991-95

- B. A. in Zoology
  Miami University, Oxford, Ohio
  Cum Laude with University Honors
  1987-91

Employment Experience:

- Radiology Associates of Northern Kentucky
  Managing partner
  Regional multispecialty radiology and imaging group
  2001-Present

  Director Vascular & Interventional Associates
  Division of Radiology Associates of NKY
  Private practice VIR group
  2003-Present

  Director VIA Vein Center
  Comprehensive Vein Center
  2013-Present

Chief of Vascular & Interventional Radiology
St. Elizabeth Health System
2003-Present

Director IR Spine Intervention
St. Elizabeth Spine Center
St. Elizabeth Health
2009-2016

Physician Trainer for Spine Intervention
Stryker International
2011-2015

Hospital Affiliations:

- St. Elizabeth Health
  Edgewood Campus
  1 Medical Village Drive
  Edgewood, Kentucky 41017
  859-344-2000

- St. Elizabeth Health
  Covington Campus
  401 East 20th Street
  Covington, Kentucky 41014
  859-292-4000

- St. Elizabeth Health
  Ft. Thomas Campus
  85 North Grand Avenue
  Ft. Thomas, Kentucky 41075
  859-572-3100

- St. Elizabeth Health
  Florence Campus
  7380 Turfway Road
  Florence, Kentucky 41042
  859-962-5200

Private Practice Office:

- Vascular and Interventional Associates
  VIA Vein Center
  Center for Spine Health

375 Thomas More Parkway
Crestview Hills, KY 41017
859-341-4841

Certification:

- ABR Certified in General Diagnostic Radiology 1999

  ABR CAQ Board Certification
  Vascular and Interventional Radiology 2001

  ABR MOC/CAQ 10yr Recertification
  Vascular and Interventional Radiology 2011

- Kentucky License #35686
  Ohio License #4536
  Indiana License #010682666A

Professional Organizations:

RSNA: 1995
ARRS: 1995
ACR: 1998
SIS: 2010
SIR: 1999
ACP: 2015

Publications:

Hurst DR, Forauer AR, Bloom JR et al: Diagnosis and Endovascular Treatment of Iliocaval Compression Syndrome. J Vasc Surg 34(1):106-13, 2001.

Hurst DR, Kazerooni EA, Williams DM, Stafford-Johnson D, Platt JF, Prince MR: Diagnosis of Pulmonary Embolism: Comparison of MR Angiography and CT Angiography in Canines. *JVIR* 10:309-318, 1999.

Dong Q, **Hurst DR**, Wienmann HJ, Chenevert TL, Londy FJ, Prince MR: Magnetic Resonance Angiography With Gadomer-17: An Animal Study Original Investigation. *Investigative Radiology* 33:699-708, 1998.

Donnelly LF, **Hurst DR**, Strife JL, Shapiro RM: Plain Film Assessment of Pulmonary Flow in the Neonate with D-Transposition of the Great Vessels. *Pediatric Radiology* 25:195-7, 1995.

Research:

VOYAGER PAD Study: An international, multicenter, randomized, double-blind, placebo-controlled phase 3 trial investigating the efficacy and safety of rivaroxaban to reduce the risk of major thrombotic vascular events in patients with symptomatic peripheral artery disease undergoing lower extremity revascularization procedures. Lead Investigator St. Elizabeth Health System 2014-present.

ATTRACT Study: a multicenter randomized trial to evaluate pharmacomechanical catheter-directed thrombolysis for the prevention of postthrombotic syndrome in patients with proximal deep vein thrombosis. Lead Investigator St. Elizabeth Health System 2013-present.

The CAPTURE registry: analysis of strokes resulting from carotid artery stenting in the post approval setting: timing, location, severity, and type. Co-investigator St. Elizabeth Health System 2005-2007.

The Fibroid Registry for outcomes data (FIBROID) for uterine embolization. Lead Investigator St. Elizabeth Health System 2001-2005.

References:

Brad Miller, M. D., President of Radiology Associates of Northern Kentucky, Saint Elizabeth Health, 859.331.5770

James Roebker, M. D., Chairman of Dept. of Radiology, Saint Elizabeth Health, 859.331.5770

David M. Williams, M. D., Professor of Radiology, Vascular and Interventional Radiology, University of Michigan Medical Center. 734.936.4483

James H. Ellis, M. D., Professor of Radiology, Associate Chairman of Department of Radiology, University of Michigan Medical Center. 734.936.4347

Prior Testimony

1. Susan Gail Smith v. St. Mary's Medical Center et al. 8/11/2015
2. Barbara Bongiorno v. Phillip Adler M. D.; St. John Macomb Hospital 1/21/2016
3. James Alley v. Hillcrest Medical Center et al. 3/15/16
4. Edith Fish v. Diallo et al. 11/7/2016
5. Austin v. CR Bard Inc. 8/19/16
6. Austin v. CR Bard Inc. 11/16/16

List of Fees

1. My current fee for the following medical legal activities is $500.00 per hour. This includes medical records review, review of depositions, literature searches, consultation time, preparation for deposition and trial testimony, oral or written reports, all travel time (billed as portal to portal), or any miscellaneous task as requested by client.
2. My current fee for all local deposition and trial activities is $750.00 per hour.
3. All out of area travel that requires an overnight stay is billed at $6000.00 per day. If I have to use a half day for travel or return from the location of trial or deposition, that will be billed at 3000.00 per half day. If I must cancel an entire office day to provide the requested services, an additional fee of $2000.00 per clinic/work day will be charged. Trial and out of area fees must be paid in advance of the date of travel.